FEDERAL FOOD IRRADIATION DEVELOPMENT AND CONTROL ACT OF 1985

HEARING

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

OF THE

COMMITTEE ON AGRICULTURE HOUSE OF REPRESENTATIVES

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[1] Effective only for the first session of the Ninety-ninth Congress.

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FEDERAL FOOD IRRADIATION DEVELOPMENT AND CONTROL ACT OF 1985

MONDAY, NOVEMBER 18, 1985

HOUSE OF REPRESENTATIVES,
SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE,
COMMITTEE ON AGRICULTURE,
Washington, DC.

The subcommittee met, pursuant to call, at 9:15 a.m., in room 1302, Longworth House Office Building, Hon. Berkley Bedell (chairman of the subcommittee) presiding.

Present: Representatives Brown, Panetta, Penny, Roberts, Morrison, Gunderson, and Evans of Iowa.

Also present: Representative E (Kika) de la Garza, chairman of the committee.

Staff present: Phillip L. Fraas, counsel; John E. Hogan, minority counsel; Glenda L. Temple, clerk; Bernard Brenner, Anita R. Brown, Timothy J. Galvin, and Gary R. Mitchell.

Mr. BEDELL. The subcommittee will come to order.

Senator Harkin has another meeting. Several of us have some very lengthy opening statements, but in view of his needs we will go ahead and hear from Senator Harkin first, and then we will have opening statements from members of the subcommittee. We are glad to have you back, Tom. We miss having you sit on our Agriculture Committee here in the House of Representatives. We trust you are going to straighten everything out in the Senate now that you are over there.

STATEMENT OF HON. TOM HARKIN, A U.S. SENATOR FROM THE STATE OF IOWA

Senator HARKIN. Thank you, Mr. Chairman.

It is an honor to be back before the subcommittee on this side. We are taking up the agriculture bill this week, and the Senate hopefully will do it justice. I do appreciate your permitting me to go first. I have another appointment that I have to rush to.

Several years ago, Mr. Chairman, when I was a member of this committee, I can remember the Department of the Army came in and——

Mr. BEDELL. Excuse me. Mr. Roberts wants to have an opportunity to welcome you.

Mr. ROBERTS. I just wanted to welcome you.

Senator HARKIN. He wants to tell me how much he misses me too.

Mr. ROBERTS. Of course, I miss you. Anybody who has been such a staunch supporter of summer fallow, such a help to the wheat producer, I wanted to officially welcome to the subcommittee and say welcome back.

In talking with Senator Zorinsky and Senator Dole, they said it might be possible to get a farm bill by the end of this week. Would that be your feeling?

Senator HARKIN. I wish we had it 3 weeks ago.

Mr. ROBERTS. I certainly hope we can make some progress, and welcome back.

Senator HARKIN. Senator Dole made the commitment we would take it up today and not get off it until we finish it. As long as there is no intervening business, we ought to finish it this week. I don't think there will be any amendments on summer fallow.

Thank you. I do want to recognize Congressman Morrison who has really been a leader in this whole area for a number of years. I compliment him for that, for his bill that he introduced in the last Congress and again in this Congress. Both Congressman Morrison and Senator Gorton, on the Senate side, have really been leaders in this area, and, of course, I am supportive of both pieces of legislation, H.R. 696 and S. 288, the Senate companion bill. I am hopeful, Mr. Chairman, that both bills will receive expeditious hearings, and markup.

As I said, Mr. Chairman, several years ago I remember the Department of the Army came in when I was a member of this committee and brought some irradiated food in for us to eat. I can remember eating some processed meat I think it was bacon or ham that had been irradiated and kept on the shelf in a vacuum-sealed package I think it was preserved for 7 years, if my memory serves me correctly. We ate it, and I had never heard of such a thing. I thought to myself at the time: Why aren't we pursuing things like this?

So little bit by little bit, more and more, people started asking questions about it. We have now reached the point where I think this is a really viable alternative and a viable supplement to the kinds of food preservation techniques that we now use.

Right now about 24 foreign countries are using irradiation, and some of them have much higher levels than what has recently been approved by the FDA for use in this country. It is something that I think will go a long way toward helping us not only in the preservation of food but increasing the shelf life without adding harmful chemicals and will also I think serve to expand our export markets. It will give us a new market for our foods overseas.

Mr. Chairman, there is a lot of talk about perhaps harmful side effects from irradiation. I want to make it very clear from the outset that I believe all safety precautions ought to be taken with the transport and the use of irradiators, whether it is cobalts or cesium, or whatever it might be. I understand the justifiable fear in the public's mind about the use of these materials especially in regard to transport. But, we have proven in the past that it can be done. It can be done safely and without any public exposure.

I want to point out the observation that food irradiation is like using an industrial sized microwave oven. You apply energy to food. It kills microorganisms. But, no thing is kept in the food.

When you use irradiation to kill organisms in the food, no radiation remains. So we have to begin to allay the public's fears in their minds that something happens in the food that can cause harm later on.

Believe me, Mr. Chairman, I am sure you know as well as I do about a lot of the chemicals that are now being added to food: Ethylene dibromide, that was being used to fumigate grain, which we know is a highly cancer-causing substance, to a lot of other chemicals that are being used to enhance the shelf life of food. I think the public would be better served if they were to understand the difference between adding chemicals which they seem readily to accept right now to preserve and enhance food color, flavor, shelf life, and what can be done with food irradiation. I think if they understand the difference, we would find a lot more public support for the whole process of food irradiation.

I only have one copy, Mr. Chairman. Perhaps you have seen it and other members have. It is a little booklet put out by CAST, the Council for Agricultural Science and Technology, from Iowa State University. It was put out in March of this year. It is comments from CAST on food irradiation. I think it lays out the whole scenario about what food irradiation is and what it does much better than any other short publication that I have seen. I don't know if you have seen this or not, but I will leave it here, and you can just pass it around. I think it is really a fine outline of what food irradiation is.

Mr. Chairman, there are about 30 commercial irradiators now operating in the United States, so we have operating experience. They are mostly used to sterilize equipment for hospitals. There are some sterilizing of food that is used for people with certain immune system problems. Now we are starting to see irradiation of spices to kill insect infestations. There are also some experimental irradiators now in use.

Mr. Chairman, the Food and Drug Administration has, as you know, approved low-level food irradiation for spices and pork. Pork irradiation will not proceed until the Department of Agriculture provides labeling and other regulations. I hope we can see those regulations by early next year at the latest. I know some of the people from the Department are sitting behind me. I don't mind labeling. We label foods already as to their contents and that is good. I support that.

I would hope that we can reach a consensus on meaningful labeling of food irradiation without unduely scaring the public that something has remained in the food. I have even heard people, on any food that is irradiated on which you put the radiation symbol, that you would find near an x-ray unit or something with a warning, "This food has been irradiated, may cause high levels of radiation." That is simply not true.

I think that would be highly counterproductive, but I see nothing wrong with a label that would say how the food has been preserved as long as labeling is also done on food as to the chemicals that are put in the food to preserve it over a long period of time. If they are both set out in the same manner, I think people would have a better idea of what is being done to preserve their foods.

So again I would hope that the labeling for food irradiation would be similar to that which is used right now to outline all of the ingredients that are already in the food.

Well, Mr. Chairman, I will sum up the rest of my testimony by saying that we have an opportunity here to move ahead very rapidly not only on low levels of irradiation for pork and spices, but for higher levels of irradiation, so we can fumigate all of our grain, preserving it for longer periods of time, increasing the shelf life of foods, and enhance our markets abroad. It is something we have fallen behind on in this country.

There is no reason why we have to fall behind in it, and I hope this committee will take expeditious action on it.

Thank you.

[The booklet follows:]

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FOOD IRRADIATION

COMMENTS from CAST

1985-2
March 1985

Council for Agricultural Science and Technology

Council for Agricultural Science and Technology (CAST)

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American Dairy Science Association
American Forage and Grassland Council
American Meat Science Association
American Meteorological Society
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American Society of Agricultural Engineers
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Weed Science Society of America
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On the cover: Irradiated foods make a delectable dinner — rolls prepared from flour irradiated for insect disinfestation, beef steak sterilized with ionizing radiation after vacuum packing in a flexible pouch, mushrooms irradiated to lengthen their shelf life, and a baked potato irradiated to prevent sprouting during storage.

FOOD IRRADIATION[1]

Mention radiation to the average American, and you conjure up images of laser guns zapping comic book villains with deadly rays, ghostly medical X-ray images, and atomic bombs. Radiation suffers from a negative (if unrealistic) public image. For the food industry, however, radiation is essential, and certain kinds of radiation can be a powerful and economical means of preserving foods and keeping them wholesome. For consumers, radiation used as a preservative can provide food products with less microbial contamination and a longer shelf life. This adds up to better health and lower food costs.

What Is Electromagnetic Radiation?

Electromagnetic radiation is energy that moves through space at the speed of light by simultaneous variation of the intensity of electric and magnetic fields. The intensity of the radiation at a particular point changes periodically, and the period may be represented by either the number of times per second the electromagnetic field makes a complete excursion and returns to its original condition (the frequency) or the distance in meters (1 meter = 1.1 yards) between corresponding points on two successive waves (the wavelength). Both methods are used, and their relationship is indicated in the accompanying diagram, where the velocity of propagation of the waves through space (3×10^8 meters per second) is equal to the product of the frequency in periods or cycles per second (hertz) and the wavelength in meters. The diagram shows both the "kinds" of electromagnetic radiation and the uses that are made of certain portions of the spectrum.

Wavelengths of electromagnetic waves cover a great range, and several portions of the spectrum are given different names. The longest are radio waves. They range from many meters down to one-thousandth of a meter. The shortest radio waves overlap infrared radiation. Infrared radiation, visible radiation (light), and ultraviolet radiation occupy successively shorter wavelengths. X-radiation overlaps ultraviolet radiation, and gamma radiation overlaps both ultraviolet radiation and X-radiation. Not shown in the diagram is cosmic radiation, which has wavelengths shorter than those of gamma radiation. Also not shown is another kind of radiation, accelerated electrons.

Radiation and Food Production

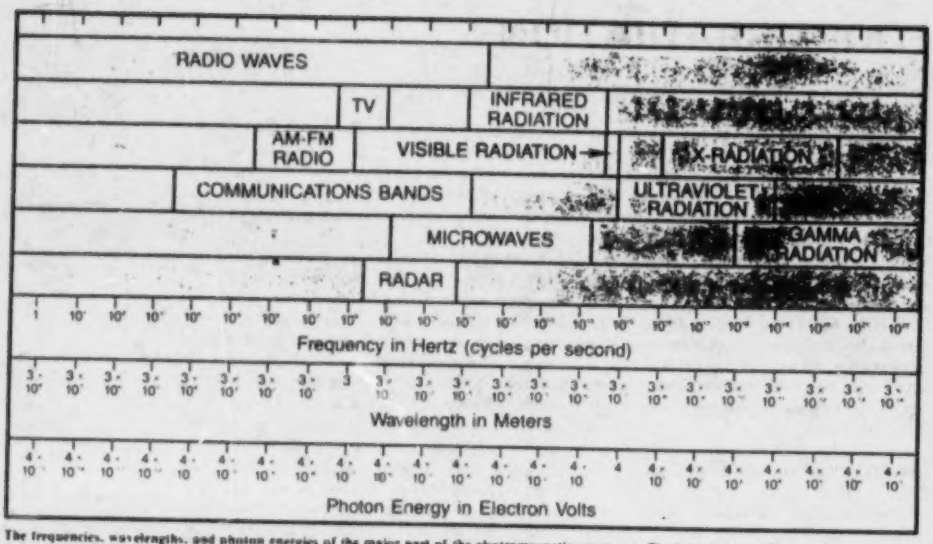
Electromagnetic radiation plays an essential role in food production. Some of the energy from the visible light range of the electromagnetic spectrum is captured by plants in the process of photosynthesis. The light energy is converted to chemical energy, which is stored in the organic compounds produced by plants. This stored chemical energy is essential for animal and human life, and it functions as the origin of the petroleum, natural gas, and coal we use as sources of stored energy. Additionally, plants and animals, from which human foods are derived, are all grown under exposure to electromagnetic radiation in the ultraviolet, infrared, and other portions of the electromagnetic spectrum.

Radiation and Food Processing

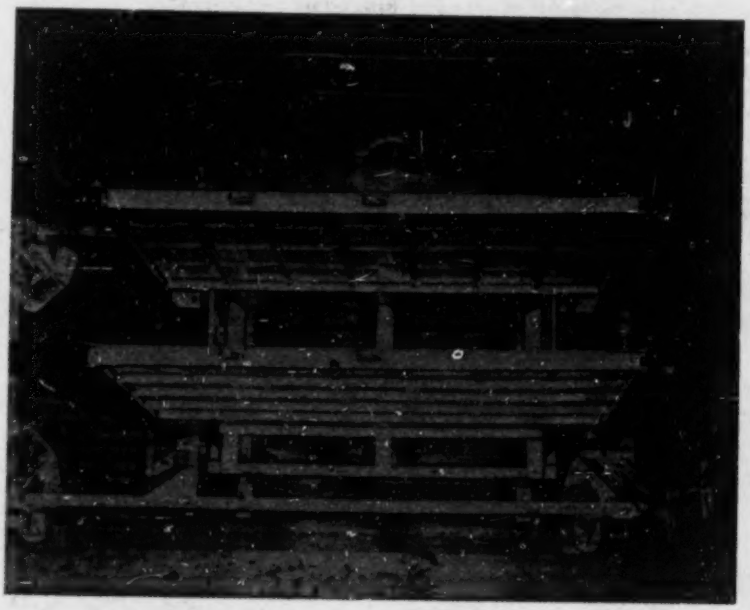
Broiling and baking are accomplished by electromagnetic radiation in the infrared range. The energy moves through space

---

[1] Prepared by Julius M. Coon, Emeritus Professor, Department of Pharmacology, Thomas Jefferson University, Philadelphia, Pennsylvania; Edward S. Josephson, Senior Lecturer, Department of Nutrition and Food Science, Massachusetts Institute of Technology, Cambridge, Massachusetts; and Eugen Wierbicki, Research Leader and Supervisory Research Food Technologist, Eastern Regional Research Center, Agricultural Research Service, U.S. Department of Agriculture, Philadelphia, Pennsylvania. The opinions expressed are those of the authors and are not necessarily endorsed by the Agricultural Research Service or the U.S. Department of Agriculture.



The frequencies, wavelengths, and photon energies of the major part of the electromagnetic spectrum. The boundaries of the named segments are more or less arbitrary, and there is now some tendency to reduce the overlapping by defining the range between TV and infrared radiation as microwaves and the range between visible radiation and X-radiation as ultraviolet



A cobalt-60 gamma irradiation unit shown resting in 25 feet of water for radiation shielding. For irradiating food, a remote-control mechanism lifts the radiation source from the water. The food loaded on special carriers then passes around the unit at a preset speed to receive the intended dose of the ionizing energy from the cobalt-60 source.

2

from the source to the food. Broiling and baking have been used for centuries as traditional methods of food preparation. The more recent exercise of cooking by microwave was readily accepted to be as safe as broiling a steak or baking a cake in a gas or electric oven.

Fresh meats, poultry, and fish, properly irradiated with gamma rays, X-rays, or accelerated electrons, can be freed of bacteria and other microorganisms, including such pathogens as *Salmonella*, giving them a longer shelf life under refrigeration. Cooked meats that are sterilized by ionizing radiation after they have been sealed under vacuum in economical containers can be preserved as long as heat-sterilized meats without refrigeration.

The banning of ethylene dibromide (EDB) as a fumigant has given new impetus to the search for ways to control insects in plant products. Irradiation effectively controls insects in stored grain and can substitute for some uses of EDB on fresh fruits and vegetables.

Ionizing Radiation

The scales in the diagram of the electromagnetic spectrum show how the energy of the radiation increases as the wavelength decreases. As the energy of the radiation multiplies, the greater is its tendency to cleave the food molecules with which it interacts into smaller ionized or electrically charged particles. Light energy has this property to a small degree, and the property becomes more pronounced as the wavelength of the electromagnetic radiation decreases. Gamma radiation, accelerated electron radiation, and X-radiation have very short wavelengths and a relatively strong tendency to produce ions. As a result, they are often called ionizing radiation.

Treating Foods With Ionizing Radiation

The value of ionizing radiation in food preservation and pest control is that in proper doses it can split enough of the molecules in the bacteria and other living organisms in certain foods so they are no longer functional, without at the same time splitting so many of the molecules in the foods that the foods are damaged. The ionizing radiation used to treat bulky food products is almost exclusively gamma rays that are emitted by decay of radioactive cobalt or cesium.

Foods can be treated with accelerated electrons and X-rays as well as with gamma radiation. On the microscopic or atomic level, the effect is the same. They all cleave some molecules into smaller ionized particles. But the penetrating power of electrons is very limited. Gamma rays with energy of 1.3 million electron volts can penetrate 20 to 30 centimeters (8 to 12 inches) of water, while electrons with energy of 10 million electron volts (the maximum energy proposed for irradiating foods without inducing measurable radioactivity) can pass through only about 3.5 centimeters (1.4 inches) of water. The relatively poor penetration of electrons, therefore, limits their practical application in food preservation and pest control to foods that can be irradiated in layers no more than 3.5 centimeters thick in specially constructed units.

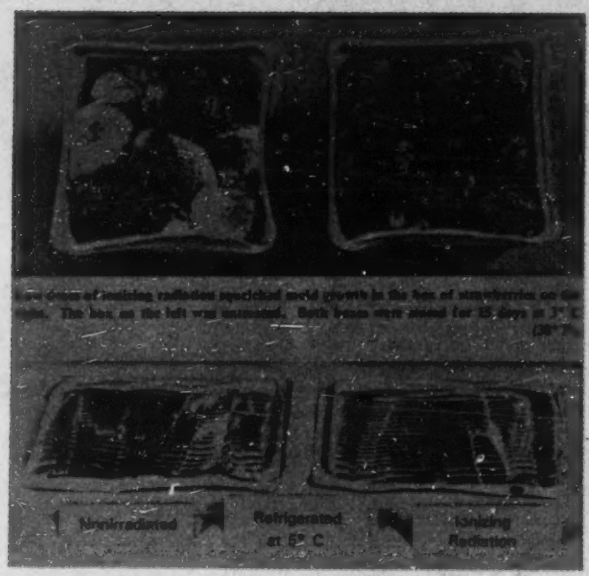
Processing of foods by ionizing radiation for preservation and pest control has been approved in many countries. But in the U.S., only minor uses have been approved, including irradiation of spices to reduce the count of microorganisms, irradiation of wheat and wheat flour to control insects, and irradiation of potatoes to inhibit sprouting. Development and use of the technology in the U.S. has been inhibited by a number of problems.

The Psychological Problem

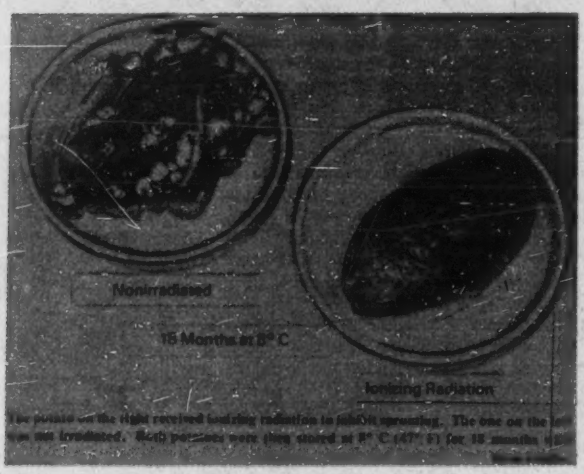
Excessive exposure of humans to ionizing radiation may produce cancer, other medical problems, and death. Humans need special protection when sources of strong ionizing radiation are used. Visible light radiation can be seen, and infrared radiation can be felt. But ionizing radiation in moderate amounts can neither be seen, nor felt, although it may have profound health consequences that occur later. No wonder people view it as a mysterious and lethal force (1).

The hazard of excessive human exposure to ionizing radiation has tended to be linked psychologically to the process of exposing foods to ionizing radiation. Public concerns fall into two categories. One is a general aversion to any use of nuclear energy and the radiation it produces. Second is the fear that treating foods with radiation may make them unhealthful.

There have been two questions about



Ionizing radiation is a potential alternative to sodium nitrite for preserving bacon. Both packages of bacon were treated with salt, vacuum packed, and refrigerated 90 days at 5° C (41 F). The brighter, fresher bacon on the right received 10 kilograys of ionizing radiation at 5° C after packaging. Ionizing radiation controls the bacteria that cause botulism, making possible the elimination or drastic reduction of the nitrite addition in bacon during processing prior to irradiation; this eliminates or greatly reduces the possible formation of nitrosamines when bacon is fried at high temperatures.



health effects. One is that if direct exposure to ionizing radiation is hazardous to humans, isn't indirect exposure also hazardous when one eats foods that have been treated with ionizing radiation? This anxiety about exposure to radiation is without scientific foundation. Ionizing radiation is merely radiant energy. It disappears when the source is removed, the food products that have been treated are not made radioactive, and there is no radiation hazard in consuming them.

Another worry is how do we know if we have tested for all possible hazardous substances that may have been created in foods by irradiation and that we have verified that no hazard exists? This question is more serious than the one about the alleged radiation hazard. Ionizing radiation does split some molecules in foods, causing changes in chemical composition. The scientific and toxicological problems raised by this question are discussed following the legal roadblock.

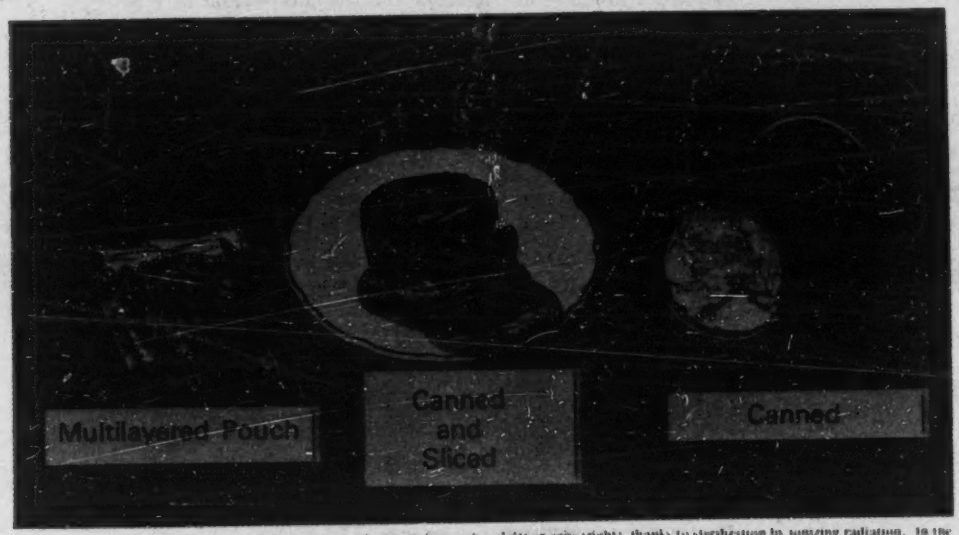
The Legal Roadblock

Enough public uncertainty existed about the use of ionizing radiation for treating foods to cause the Congress to act. In the *Food Additives Amendment of 1958*, the Congress classed ionizing radiation with food additives on the basis that it may affect the characteristics of food. Because of the wording of this law, the Food and Drug Administration, prior to approving any use of ionizing radiation as a food treatment, had to be assured that the proposed use satisfied the requirements for safety of chemical food additives. This legal roadblock created a toxicological problem and indirectly an economic problem.

The Scientific Problem

Scientifically, the question about testing for all possible hazardous substances and verifying that no hazard exists can never be fully answered. No matter how many substances have been found and proved to be innocuous at the levels present, one can never be sure that all the substances formed as a result of food irradiation have been identified or that they are all harmless. The same, of course, can be said for foods processed by heat. Heating creates more chem-

Beef steak preserved by ionizing radiation for use by the Apollo-Soyuz astronauts. Corned beef, smoked turkey breasts, ham, and pork chops similarly preserved were also served on that space mission. Foods preserved by ionizing radiation are now used routinely on space flights.



Cooked roast beef can be stored indefinitely without refrigeration in pouches (left) or cans (right), thanks to sterilization by ionizing radiation. In the center, some of the canned product has been sliced ready for use, either as cold, canned roast beef or for reheating as part of a warm meal.

ical changes than does irradiation with the high doses needed for sterilization.

The Toxicological Problem

An insurmountable experimental problem is created by the fact that the changes in chemical composition of foods associated with ionizing radiation are diverse and that the products are not separable from the foods for testing in the proportions in which they exist. In gauging the risk of using a chemical additive in our food supply, the procedure used by toxicologists is to feed different doses of the substance to test animals to find the relationship between the doses ingested and the responses of the test animals. The maximum dose that does not produce a harmful effect is found from the response curve. This information is used to estimate a practical margin of safety, that is, the difference between the maximum "no-effect level" of intake by the test animals and the maximum level that should be allowed for human consumption.

The standard toxicological procedure to estimate a margin of safety for human consumption works well for chemical food additives, which are expected to remain in foods to serve a specific purpose, but it is unrealistic for irradiated foods. Although new chemical products from irradiation can be identified, their concentrations are very low, generally measurable in parts per million or parts per billion. Some of the new products could be added in increasing quantities for testing purposes like chemical food additives, but it is unlikely that all the new products will ever be known, and certainly they cannot be added in increasing quantities in precisely the proportions in which they occur. This means that the standard kind of evidence needed to verify that the levels of chemical food additives are safe cannot be obtained for the substances that have been formed in foods by irradiation.

The texture of meat and poultry products is often better when they have been sterilized by ionizing radiation than by heat.

However, in 30 years of extensive animal feeding studies with irradiated foods in the U.S. and other countries and on several different species of animals, there has been no confirmed evidence of any harmful effect of irradiating food with the doses needed to control insect pests and bacteria. It has not been proved that the effects of ionizing radiation on the chemical composition of foods are more extensive or more dangerous than those of any of the other commonly accepted forms of radiant energy, such as infrared radiation (heat) or microwaves, used in food preparation.

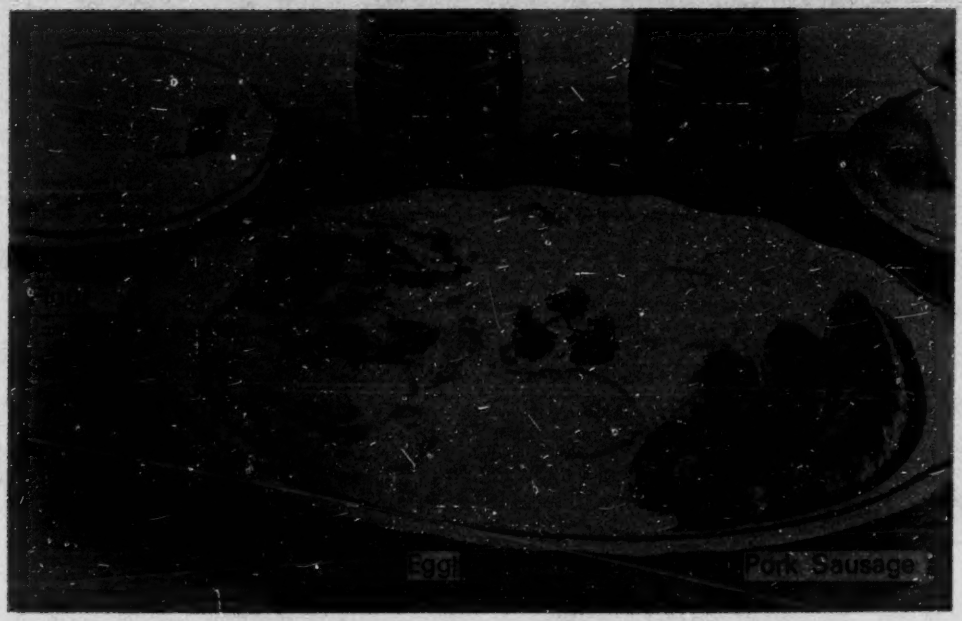
The chemical changes produced in foods by high (sterilizing) doses of ionizing radiation are minor. None of the compounds found to be produced by ionizing radiation are unique products of the irradiation. Rather, they are identical with naturally occurring substances, and they are found in smaller quantities than are produced when foods are cooked.

The Economic Problem

The experimental impossibility of obtaining the toxicological evidence required for approval of irradiation in the sense of a chemical food additive creates an economic problem. Much additional supplementary evidence is needed to obtain regulatory sanction for use of a specific dose of radiation on a particular product. Because of the expense involved and the lack of assurance that the proposed procedure would win approval from the Food and Drug Administration, companies generally are unwilling to invest the money required. This discourages the use of irradiation. As a consequence, more energy is needed to refrigerate and prepare food, and processors must use additional amounts of chemicals as fumigants and preservatives.

Irradiation Not For Every Product

Some food products are better candidates for irradiation than others. Generally, a product that is dry, such as grain, can tolerate more radiation without detrimental



The irradiated breakfast — hot biscuits from flour irradiated for insect disinfestation, fried potatoes made from raw potatoes irradiated to prevent sprouting, fresh eggs irradiated to control *Salmonella*, and prefried pork sausage links vacuum packed and stored without refrigeration for two years after irradiation with a sterilizing dose.

effects than a moist product, such as fresh fruits, vegetables, and meats.

At low doses (up to 1 kilogray [2]), beneficial effects of irradiating food commodities of plant origin include (a) inhibition of sprouting of tuber, bulb, and root crops, including potatoes and onions; (b) control of insects in some fresh fruits and vegetables, nuts, dried fruits and vegetables, cereal grains, and legume seeds; and (c) delay of ripening of certain tropical fruits.

At higher doses (between 1 and 3 kilograys), irradiation has bactericidal and fungicidal effects that can be useful for controlling decay in some commodities that suffer little or no injury from irradiation. Used on fresh (chilled) or frozen meats, poultry, fish, and shellfish, such doses can increase the shelf life under refrigeration and can greatly reduce the level of bacterial pathogens, such as *Salmonella*. Fresh plant commodities with high water content, however, generally do not tolerate irradiation doses exceeding 3 kilograys without detrimental effects. Irradiation in doses of 2 to 4 kilograys, which are effective in controlling decay of fresh fruits and vegetables, adversely affects their quality, especially texture.

On the other hand, irradiation at doses of 4 to 10 kilograys is a very effective treatment for reducing the numbers of microorganisms in spices, dried vegetables, and frozen foods (shrimp, beef, poultry) without detrimental effects on their flavors. This treatment also modifies the textural quality of dried vegetables and legumes and has been shown to reduce the cooking time.

The Verdict

A large and impressive collection of scientific evidence from across the years and the world suggests that properly applied doses of irradiation are no more harmful than any of

the conventional processing and cooking techniques. And irradiated food is far less dangerous (or distasteful) than spoiled or buggy food.

References and Further Reading

1. Ultraviolet radiation has long been known to cause cancer of the skin in humans. Although ultraviolet radiation (like gamma radiation) cannot be seen, no concern has ever developed about possible human hazards from the exposure of plants to ultraviolet radiation during their growth before they are consumed as food.
2. The kilogray has been adopted as the standard measure of ionizing radiation dosage. One kilogray is equivalent to 100 kilorads. The kilorad is a unit of radiation dosage used previously. One kilogray is equivalent also to one kilojoule of radiation energy absorbed by one kilogram of food and to 0.24 gram calorie.
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4. J. M. Coon and E. S. Josephson. 1984. Is radiation a food additive? COMMENTS from CAST 1984-3.
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7. Joint FAO/IAEA/WHO Expert Committee. 1981. Wholesomeness of irradiated foods. World Health Organization, Technical Report Series 659. Geneva, Switzerland.
8. E. S. Josephson and M. S. Peterson (Eds.). 1982 and 1983. Preservation of Food by Ionizing Radiation. Volume I (378 pages, 1982), Volume II (343 pages, 1983), and Volume III (275 pages, 1983). CRC Press, Boca Raton, Florida.
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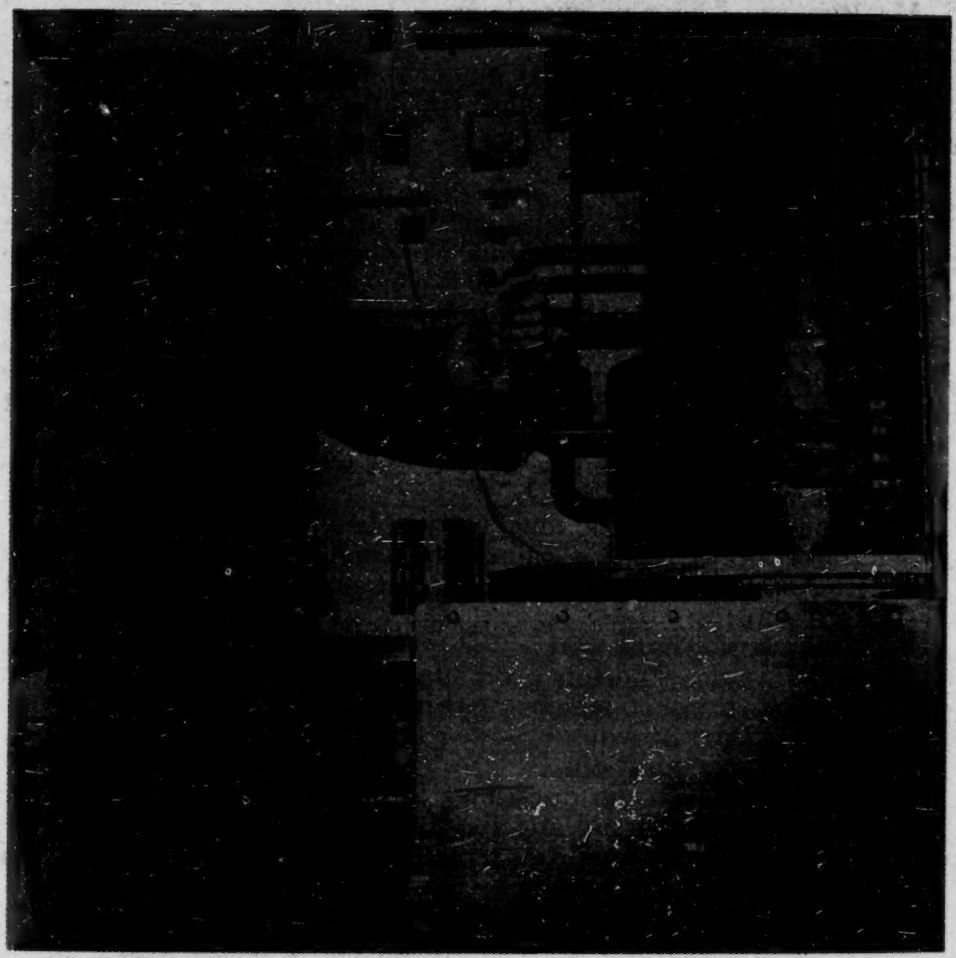
16. K. Tsuji. 1983. Low-dose cobalt 60 irradiation for reduction of microbial contamination in raw materials for animal health products. Food Technology 37(2):48-54.
17. E. Wierbicki. 1981. Food irradiation could foster microbiological standards. Food Development 15(12):26, 30, 32.



Dr. Eugen Wierbicki standing *beside* the apparatus used to irradiate foods in research at the U.S. Department of Agriculture's Eastern Regional Research Center in Philadelphia.

Mr. BEDELL. Thank you for your testimony. Mr. Roberts.

Mr. ROBERTS. I have no questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. No particular question, Mr. Chairman.

I just wanted to thank Senator Harkin for his leadership in the Senate on this particular issue and look forward to working with you.

Tom, are there prospects over there for hearing or for perhaps some movement on this legislation? We know they were supportive of the appropriation that is included in the 1986 budget, but can we go farther than that as far as that is concerned?

Senator HARKIN. The last time I talked to Senator Gorton, he was most hopeful that we could have some hearings on that on the Senate side. As you know, in the appropriations process, we were supportive of irradiation I think, obviously, the legislation is not going to move this year on either side, the House or the Senate. I don't know. Maybe you know more about what is happening in the House than I do.

Mr. MORRISON. Depends how long you keep us here, Senator.

Senator HARKIN. That is right. I just don't see any possibility of it moving this year. But I do see a possibility of it moving next year, I sure do.

Mr. MORRISON. Thank you.

Senator HARKIN. There is good support in the Senate. Just from my talking with my colleagues, I think that there is good support.

Mr. BEDELL. Mr. Brown.

Mr. BROWN. No questions.

Mr. BEDELL. I have no questions, Tom, except to thank you for your interest in this issue and for the leadership you have shown.

Senator HARKIN. Thank you again, Mr. Chairman. Thank all of you for permitting me to go first. Thank you.

OPENING STATEMENT OF HON. BERKLEY BEDELL, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF IOWA

Mr. BEDELL. We now will have the opening statements of subcommittee members. First, I would like to welcome everyone here as we consider H.R. 696, "The Federal Food Irradiation Development and Control Act of 1985," introduced by our colleague, Mr. Morrison, who is here with us today. I think this hearing is particularly timely in view of the Food and Drug Administration's recent approval of low-level irradiation to help control trichinosis in pork, and FDA's anticipated decision on the irradiation of fruits and vegetables.

Although FDA has approved the irradiation of pork, USDA's Food Safety and Inspection Services [FSIS] now must give its consent because FSIS has authority over meat and poultry inspections. FSIS must evaluate the safety of pork irradiation and determine any labeling and handling requirements for the irradiated product.

This regulatory activity apparently has generated increased consumer interest in examining the safety and labeling questions associated with irradiation. Today we expect to hear from a number of witnesses on both sides of the issue, as well as from those Federal agencies with primary regulatory responsibility for irradiation. The

purpose of our hearing is to give interested public representatives an opportunity to express their views in an open manner, as well as to better inform subcommittee members about the promise and concerns raised by irradiation.

All witnesses have been strictly advised to keep their oral presentation to 5 minutes or less. We have a long list of witnesses today, and I will ask for your complete cooperation in adhering to the time limit so that we can hear from everyone and maximize the time available for questions.

I would like to emphasize that point a little bit. We have eight panels today and unless we really hold to our time limits, people at the end are simply not going to have an adequate opportunity to express their views. I will have to inform the witnesses if they have exceeded their time limit. We appreciate your being here.

[H.R. 696 and the report from U.S. Department of Agriculture follow:]

I

99TH CONGRESS
1ST SESSION

H. R. 696

To provide Federal coordination for the continued development and commercialization of food irradiation through the establishment of a Joint Operating Commission for Food Irradiation in the Department of Agriculture and through other means.

IN THE HOUSE OF REPRESENTATIVES

JANUARY 24, 1985

Mr. MORRISON of Washington (for himself, Mr. FOLEY, Mr. PRICE, Mr. ROBERTS, Mr. WATKINS, Mr. WHITEHURST, Mrs. LLOYD, Mr. WEBER, Mr. MCCAIN, Mr. SKEEN, Mr. CHANDLER, Mr. PASHAYAN, Mr. LEACH of Iowa, Mr. TAUKE, Mrs. BYRON, Mr. ROBERT F. SMITH, Mr. STRATTON, Mr. SMITH of Iowa, Mr. BEDELL, Mr. FAZIO, Mr. HILLIS, Mr. EVANS of Iowa, Mr. COELHO, Mr. VOLKMER, and Mr. LIGHTFOOT) introduced the following bill; which was referred jointly to the Committees on Energy and Commerce, Armed Services, and Agriculture

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A BILL

To provide Federal coordination for the continued development and commercialization of food irradiation through the establishment of a Joint Operating Commission for Food Irradiation in the Department of Agriculture and through other means.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SHORT TITLE

SECTION 1. This Act may cited as the "Federal Food Irradiation Development and Control Act of 1985".

FINDINGS AND PURPOSES

SEC. 2. (a) The Congress find that—

(1) irradiation of food at regulated doses is recognized by international authorities and the Department of Health and Human Services as safe and wholesome;

(2) irradiation of food inhibits or destroys the bacteria and other microorganisms which cause food to spoil and eliminates trichinosis in pork, insect pests in fruits, vegetables and grains, and food-borne pathogens, such as salmonella and botulinum in red meats, poultry, and fish products;

(3) irradiation of food is one of the substitutes for many of the post harvest fumigants including ethylene dibromide;

(4) radiation sources used for irradiation process including five MeV (million electron volts) for gamma rays and x ray, and ten MeV for electrons cannot induce added risks to consumers from radioactivity in food;

(5) irradiation of food is a process, much like cooking in a microwave oven, boiling, or freezing;

(6) additional research and development is needed to determine the optimum dose level for irradiation on

foods and the appropriate marketing factors in order to apply the benefits of irradiation to a variety of products assuring public safety;

(7) there needs to be national uniformity in the regulation of irradiation processing of food;

(8) public understanding of ionizing radiation is essential to develop widespread commercial opportunities and to promote consumer acceptance of food irradiation;

(9) irradiation is currently approved in the United States for use of spices, fresh potatoes to inhibit sprouting, wheat and wheat flour for disinfestation, and twenty-five other countries have approved application of food irradiation on at least forty different food items;

(10) there are a variety of current or potential uses for irradiation beyond processing of food, including sterilization of surgical instruments and other medical products, sterilization of baby powder, manufacture of nonstick cookware, treatment of cosmetic products, pasteurization and sterilization of sewage sludge, soil and timber fumigation, seed stimulation, processing of polymers, production of chemicals, and many others;

(11) there is an acute shortage of United States source material required for food irradiation process

and current supplies are unable to meet projected demand;

(12) the Federal Government owns byproduct material as part of our defense nuclear waste program;

(13) a significant return on investment can come back to the United States Treasury through the lease of irradiation source materials to private and public agencies;

(14) there needs to be coordination with international organizations and State governments on research, development, applications, and standards for irradiation and among the many Federal agencies involved, including the Department of Agriculture, the Department of Energy, and Food and Drug Administration, the Department of Health and Human Services, the Environmental Protection Agency, the Nuclear Regulatory Commission, the Department of Commerce, and the Agency for International Development; and

(15) there needs to be coordination between the Federal Government and the private sector for the purpose of encouraging private enterprise development and utilization of irradiation processing.

(b) The purposes of this Act are to—

(1) change the definition of food irradiation so that it is defined as a food process, subject to existing regulatory authority of the Food and Drug Administration;

(2) expand research and development of ionizing radiation in order to facilitate commercialization of a variety of beneficial use technologies;

(3) provide for education regarding food irradiation by ionizing radiation in order to promote public understanding and acceptance;

(4) provide for national uniformity in the regulation of irradiation processing of food;

(5) ensure adequate supplies of source material by providing for the safe domestic leasing of nuclear byproduct material for use in commercial applications of food irradiation and continue the current foreign nuclear byproduct distribution program; and

(6) provide for the creation of a Joint Operating Commission for Food Irradiation within the Department of Agriculture to serve as an intermediary with private enterprise, Federal and State government agencies, international organizations, and the public.

DEFINITIONAL AND REGULATORY CHANGES

SEC. 3. (a) Section 201(s) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(s)) is amended by—

(1) striking out "; and including any source of radiation intended for any such use" in the first parenthetical material;

(2) striking out "or" at the end of paragraph (4), and by striking out the period at the end of paragraph (5) inserting in lieu thereof "; or"; and

(3) adding the following new paragraph at the end thereof:

"(6) food irradiation process.".

(b) Section 201 of such Act (21 U.S.C. 321) is amended by adding the following new subsection at the end thereof:

"(bb) The term 'food irradiation process' means a food treatment in which ionizing energy is applied to raw agricultural commodities, processed foods, or other foods to destroy the organisms which cause infestation in food, to inhibit or destroy bacteria and other microorganisms which among other things cause food to spoil or make the food unwholesome, to inhibit sprouting, to retard the postharvest ripening of foods, and to improve the food's functional properties.".

(c)(1) Section 409 of such Act (21 U.S.C. 348) is amended—

(A) in subsection (a) by—

(i) inserting "or food irradiation process" after "food additive" each place it appears;

(ii) inserting "or process" after "such additives" and after "such additive";

(iii) inserting "or clause (7)" after "clause (2)(C)"; and

(iv) inserting "or having been treated by such a process" after "such an additive";

(B) in subsection (b) by—

(i) inserting "or food irradiation process" after "food additive" in paragaph (1);

(ii) inserting "for such additive" after "including" in paragraph (2)(A);

(iii) inserting "or process" after "such additive" each place such term appears except the first time it appears in paragraph (2)(B) and except in paragraphs (2)(C), (2)(D), and (3);

(iv) inserting "or the source of the food irradiation process" after "food additive" in paragraph (2)(A);

(v) inserting "or the proposed procedures and methods for conducting the food irradiation process" after the first time "such additive" appears in paragraph (2)(B);

(vi) inserting ", unless the level of the proposed food irradiation process has already been

recognized to be safe by the Secretary" before the period at the end of paragraph (2)(E);

(vii) inserting "in the case of a food additive," after "(or," and "food irradiation process or" after "for," in paragraph (3); and

(viii) inserting ", or in the case of food irradiation process, such information as the Secretary requests" before the period at the end of paragraph (4);

(C) in subsection (c) by—

(i) inserting "or food irradiation process" after "food additive" and "food additives" each place such terms appear;

(ii) inserting "or process" after "such additive" the first place it appears in paragraph (1)(A) and each place it occurs in clause (i) of the proviso of paragraph (3)(A) and in paragraph (4)(A);

(iii) inserting "or process" after "no additive" in paragraph (3)(A), after "the additive" in paragraph (3)(B), and after "an additive" in paragraph (4); and

(D) in subsection (d) by—

(i) inserting "or food irradiation process" after "food additive"; and

(ii) inserting "or process" after "such additive"; and

(E) in subsection (i) by—

(i) inserting "or food irradiation process" after "food additive"; and

(ii) inserting "or treated by such process" after "such additive".

(2) The heading of section 409 of such Act (21 U.S.C. 348) is amended by inserting "AND FOOD IRRADIATION PROCESS" AFTER "ADDITIVES".

(3) The heading of section 409(a) of such Act (21 U.S.C. 348(a)) is amended by inserting "and Food Irradiation Process" after "ADDITIVES".

NATIONAL UNIFORMITY

SEC. 4. (a) It is declared to be the express intent of Congress to require national uniformity in the regulation of irradition processing of food in order to permit national marketing of all irradiated food without jurisdictional barriers.

(b) No State or political subdivision thereof may establish or continue in effect any requirement relating to the irradiation processing of food, or to the labeling or marketing of irradiated food, which is in addition to or different from the requirements of the Federal Food, Drug, and Cosmetic Act and the Fair Packaging and Labeling Act, and the regulations and interpretations issued thereunder.

(c) Any State or political subdivision thereof may exercise concurrent jurisdiction with the Secretary of Health and Human Services over the irradiation processing of food, and the labeling and marketing of irradiated food, for the purpose of enforcing requirements identical with those established in the Federal Food, Drug, and Cosmetic Act, the Fair Packaging and Labeling Act, and the regulations and interpretations issued thereunder.

(d) Any State or political subdivision thereof may petition the Secretary of Health and Human Services to adopt by regulation as a Federal requirement any requirement relating to the irradiation processing of food or to the labeling or marketing of irradiated food.

LEASING OF NUCLEAR BYPRODUCT MATERIAL FOR FOOD IRRADIATION

SEC. 5. (a) The third sentence of section 81 of the Atomic Energy Act of 1954 (42 U.S.C. 2111) is amended—

(1) by inserting "at rates that reflect fair market value" before the comma at the end of clause (a);

(2) in clause (b), by inserting "commercial or other" before "use";

(3) by striking out "and" at the end of clause (b); and

(4) by inserting before the period at the end thereof the following: ", and (d) will encourage commercial applications of byproduct material as defined in section

11 e. (1), particularly as a source for food irradiation process".

(b) The fourth sentence of section 81 of such Act (42 U.S.C. 2111) is amended—

(1) by striking out "either"; and

(2) by inserting ", in commercial applications of food irradiation process," after "development".

(c) The changes made by this section to section 81 of such Act (42 U.S.C. 2111) are intended to apply only to byproduct material produced as a result of the Defense Nuclear Waste Program.

ESTABLISHMENT OF JOINT OPERATING COMMISSION FOR FOOD IRRADIATION

SEC. 6. (a) There hereby is established within the Department of Agriculture a commission to be known as the Joint Operating Commission for Food Irradiation (hereafter in this section referred to as the "Commission"). The Commission shall carry out the functions specified in subsection (c), subject to the supervision of the Secretary of Agriculture.

(b)(1) The Commission shall consist of eight members as follows:

(A) one individual, appointed by the President, who is representative of the interests of the general public and who is not an officer or employee of the Federal Government;

(B) one individual appointed by the Secretary of Agriculture from among the officers and employees of the Department of Agriculture;

(C) one individual appointed by the Secretary of Health and Human Services from among the officers and employees of the Department of Health and Human Services;

(D) one individual appointed by the Secretary of Energy from among the officers and employees of the Department of Energy;

(E) one individual appointed by the Administrator of the Environmental Protection Agency from among the officers and employees of the Environmental Protection Agency;

(F) one individual appointed by the Nuclear Regulatory Commission from among the officers and employees of the Nuclear Regulatory Commission;

(G) one individual appointed by the Secretary of Commerce from among the officers and employees of the Department of Commerce; and

(H) one individual appointed by the Administrator of the Agency for International Development from among the officers and employees of the Agency for International Development.

(2) The appointments of the initial members of the Commission shall be made before the expiration of the ninety-day period following the date of the enactment of this Act.

(3) Each member of the Commission shall report directly to the authority appointing such member and each Commission member shall serve for such period of time as the authority appointing such member considers appropriate.

(4) A vacancy in the Commission shall be filled before the expiration of the sixty-day period following the date on which such vacancy occurs, and in the same manner in which the original appointment was made.

(5)(A) Any member of the Commission who is a full-time officer or employee of the Federal Government shall receive no additional pay, allowances, or benefits by reason of the service of such member on the Commission.

(B) Each member of the Commission not described in subparagraph (A) shall be paid at a rate equal to the daily equivalent of the minimum annual rate of basic pay payable for grade GS–15 of the General Schedule for each day, including travel time, during which such member is engaged in the actual performance of duties vested in the Commission. Each such member shall be reimbursed for actual expenses, including travel expenses, incurred in the course of performing such duties.

(c) It shall be the function of the Commission—

(1) to coordinate and review all research, development, and demonstration activities of the Federal Government relating to the use of irradiation in agricultural production including food irradiation process and the food irradiation process activities of the Department of Energy, except that any additional research determined by the Commission to be required for the commercialization of food irradiation process and the use of irradiation in agricultural production including postirridation monitoring and inline dosimetry shall, to the maximum extent practicable, be conducted at existing laboratories of the Agricultural Research Service of the Department of Agriculture, at land-grant institutions of higher education, and at existing Federal multiprogram laboratories;

(2) to collect and consolidate the data produced by all Federal agencies as a result of research, development, and demonstration activities relating to food irradiation process;

(3) to coordinate informational exchange and educational activities with respect to food irradiation process with appropriate Federal agencies, the States including appropriate interstate compacts, commodity groups, export trading groups, other interested private organizations, and the general public;

(4) to encourage interest and investment by private enterprises in the development and application of food irradiation process;

(5) to consider and make recommendations to decisionmaking bodies on the labeling, packaging, and handling of food products processed with irradiation;

(6) to encourage a better understanding by the general public with respect to food irradiation process;

(7) if determined by the Commission to be appropriate, to petition the Food and Drug Administration under section 409 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 348) to expand the scope of regulation allowing for commercial application of food irradiation process; and

(8) to submit annually to the Congress a report setting forth the specific progress made by and future plans of the Commission in carrying out the functions described in paragraphs (1) through (7).

(d) The Secretary of Agriculture shall provide the Commission with such staff and office facilities as the Secretary, following consultation with the Commission, considers necessary to permit the Commission to carry out its functions under this section.

(e) There are authorized to be appropriated such sums as may be necessary to carry out the provisions of this section.

○

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

December 20 1985

Honorable E (Kika) de la Garza
Chairman, Committee on Agriculture
House of Representatives
Washington, D.C. 20515

Dear Mr. Chairman:

This is in response to your request for a report on H.R. 696, a bill "To provide Federal coordination for the continued development and commercialization of food irradiation through the establishment of a Joint Operating Commission for Food Irradiation in the Department of Agriculture and through other means.".

The Department of Agriculture opposes enactment of the bill unless it is amended as recommended below.

H.R. 696 contains six sections. Sections 1 and 2 provide a short title and congressional findings and statement of purpose. Section 3 of the bill makes definitional and regulatory amendments to the Federal Food, Drug, and Cosmetic Act regarding irradiation of food. Under the Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), and the Egg Products Inspection Act (21 U.S.C. 1031 et seq.), the Secretary of Agriculture is responsible for inspecting meat, poultry, and egg products to determine if they are adulterated. Any of such products found to be adulterated would be prohibited from distribution in commerce. An article is adulterated if, among other things, it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act. Under the current law, the Secretary of Agriculture may prohibit the use of a food additive in or on a meat, poultry, or egg product if the Secretary deems it necessary, even if the food additive has been determined safe under section 409. The Secretary would have to promulgate regulations and specify why it was deemed necessary to prohibit the use of such food additive. In most instances, the Secretary would follow the studies and findings of the Food and Drug Administration that the food additive is safe. However, the Secretary might consider it necessary in a few instances to conduct an independent review of the safety of the food additive as applied to meat, poultry, or egg products. This would be the case if the Secretary felt that the findings of the Food and Drug Administration did not address adequately the impact of the food additive when used in meat, poultry, or egg products. If the independent review revealed that the food additive was unsafe or would otherwise be an adulterant when applied to meat, poultry, or egg products, the Secretary could prohibit the use of that additive in those products.

Accordingly, since the food additive provisions of section 409 are being amended to incorporate food irradiation processes, we recommend that the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act be amended to provide the Secretary with parallel authority to impose a like prohibition on the use of a food irradiation process on a meat, poultry, or egg product if the Secretary deems it necessary, even if the food irradiation process has been determined safe under section 409. Please find enclosed suggested amendments to the three inspection statutes that would accomplish this purpose. As is the case with food additives, the Secretary would have to promulgate regulations and specify why it was deemed necessary to prohibit the use of such food irradiation process.

Section 4 addresses the need for national uniformity in the regulation of irradiation of food. These matters initially are within the jurisdiction of the Department of Health and Human Services. However, as discussed above, we believe that the Secretary of Agriculture should be given independent authority to prohibit the use of a food irradiation process on a meat, poultry, or egg product. We, therefore, recommend that section 4 of the bill be amended to ensure that states or their political subdivisions may not impose requirements in addition to or different from those imposed under the Federal Meat Inspection Act, the Poultry Products Inspection Act, or the Egg Products Inspection Act. This could be accomplished by inserting on page 9, line 23, of the bill, immediately following "Federal Food, Drug, and Cosmetic Act" the following: ", the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act,". Moreover, unlike the preemption provisions of the meat, poultry and egg products inspection acts, the prohibition in this bill would go beyond state and local regulation of labeling and extend to state and local regulation of intrastate marketing. We oppose this as an unwarranted federal intrusion into matters that are legitimate state concerns.

Section 5 addresses issues, through amendment of the Atomic Energy Act of 1954, under the jurisdiction of the Department of Energy and the Nuclear Regulatory Commission. We defer to those agencies for appropriate comment on section 5.

Section 6 of the bill provides for the establishment within the Department of Agriculture of a Joint Operating Commission for Food Irradiation composed of eight individuals representing various Federal agencies and the general public. The Commission would coordinate and review all research, development, and demonstration activities of the Federal Government relating to food irradiation.

The Department of Agriculture opposes enactment of section 6 and the related statement of legislative purpose in section 2(b)(6). The proposed functions of the Joint Operating Commission for Food Irradiation (hereinafter referred to as the Commission) describe activities already being carried out by Federal agencies. The establishment of a Commission will add a new layer of authority to Federal management of irradiation technology which could serve to slow implementation of scientific developments.

Coordination of research activities and exchange of information relative to commercial implementation of irradiation technology has been done informally by an interagency working group on irradiation. More formally, the Office of Science and Technology Policy (OSTP) is considering formation of a Subcommittee on Food Irradiation under the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) which has broader representation of Executive Branch agencies than the proposed Commission. When consideration is given to the policy directing authority exercised by CIRRPC, a Joint Operating Commission for Food Irradiation is unnecessary.

The legislation would empower the Commission to collect and consolidate data produced by Federal agencies on food irradiation. Currently this service is being provided in part by the National Technical Information Service, Department of Commerce, and the National Agricultural Library, where access to the information is made available to the general public. In addition, research information developed by the Department of Agriculture is disseminated to private industry and other interested parties through published papers, presentations at meetings and seminars, other personal contacts, and coordination with the Extension Service of this Department.

Public education on food irradiation safety is an integral component of commercial marketing of food. When the capacity for commercially irradiating products in large quantities is in place, the Department, through the Extension Service, can provide information to consumers of agricultural products. However, we believe that consumer education on irradiation as a food treatment is most appropriately done by the food processing industry using the information developed by research programs and regulatory agency reviews. Toward this end, a private sector organization, the Coalition for Food Irradiation, has already been formed. Its mission is to channel the support of a broad-based group of food interests for a program to educate consumers on food irradiation and to develop opportunities where useful dialogue on food irradiation can take place.

The Office of Management and Budget advises that there is no objection to the presentation of this report from the standpoint of the Administration's program.

Sincerely,

John R Block

John R. Block
Secretary

Enclosure

Proposed Amendments to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act

1. The Federal Meat Inspection Act is amended -

(a) in section 1(m)(2)(A) (21 U.S.C. §601(m)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 1(m)(2)(C) (21 U.S.C. §601(m)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 1(m)(2)(D) (21 U.S.C. §601(m)(2)(D)) by inserting "food irradiation process," after "food additive,";

(d) in section 1(m)(7) (21 U.S.C. §601(m)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 1(r) (21 U.S.C. § 601(r)) by inserting "'food irradiation process'," after "food additive,'".

2. The Poultry Products Inspection Act is amended -

(a) in section 4(g)(2)(A) (21 U.S.C. § 453(g)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 4(g)(2)(C) (21 U.S.C. § 453(g)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 4(g)(2)D) (21 U.S.C. §453(g)(2)(D)) by inserting "food irradiation process," after "food additive,";

(d) in section 4(g)(7) (21 U.S.C. §453(g)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 4(y) (21 U.S.C. § 453(y)) by inserting "'food irradiation process'," after "'food additive',".

3. The Egg Products Inspection Act is amended -

(a) in section 4(a)(2)(A) (21 U.S.C. §1033(a)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 4(a)(2)(C) (21 U.S.C. §1033(a)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 4(a)(2)(D) (21 U.S.C. §1033(a)(2)(D)) by inserting "or food irradiation process," after "food additive,";

(d) in section 4(a)(7) (21 U.S.C. 1033(a)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 4(u) (21 U.S.C. §1033(u)) by inserting "'food irradiation process'," after "'food additive',".

Mr. BEDELL. Mr. Roberts.

OPENING STATEMENT OF HON. PAT ROBERTS, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF KANSAS

Mr. ROBERTS. Yes. Thank you, Mr. Chairman.

In the interest of time, I would ask permission my full statement be entered into the record.

As one of the original sponsors of H.R. 696, introduced by my friend, Mr. Morrison, I would hope, as the Senator has indicated, we could take all of the concerns into account and perhaps move on a markup of this legislation at the earliest opportunity. I don't think we could do that this session, but perhaps say in the next year.

I want to say that this process is an important and a safe alternative to the use of pesticides. I think perhaps the biggest issue that we will face during these hearings is the issue of labeling and consumer safety and acceptance of products that have been subjected to this process. I know there are trade associations out there who do not support labeling, but I believe it is in the long term best interest to label the product so that the consumer is aware of its use. If we don't label the products, the issue will become a lack of labeling, and I think that would be unfortunate.

I yield back the balance of my time, Mr. Chairman.

[The prepared statement of Mr. Roberts follows:]

Statement of Honorable Pat Roberts

November 18, 1985

Mr. Chairman. I commend you for calling this hearing today. The last time this Subcommittee took a look at irradiation was during the ethylene dibromide (EDB) crisis. The Subcommittee hearing was focused on alternatives to the use of EDB, and irradiation came up as a possible alternative in the protection of stored fruit and grains.

Since that hearing, there have been several developments in the area of approving irradiation for the protection of food. Of particular interest to the Agriculture Committee is the use of irradiation on pork. On July 22, 1985, the Food and Drug Administration approved irradiation of hog carcasses and pork products for trichinae control. I look forward to hearing the progress report from the Food and Drug Administration. I understand that the issue of labeling has been brought up by the Food Safety Inspection Service, of the U.S. Department of Agriculture.

Irradiation is an important and safe alternative to the use of pesticides. However, the issue of labeling and consumer acceptance of products that have been irradiated is of concern. I know that there are trade associations that do not support labeling, but I believe it is in the long-term best interest of

irradiation to label the product so that the consumer is aware of the use of irradiation. If we don't label the products, the issue will become the lack of labeling and not the advantages of the use of irradiation.

I am an original co-sponsor of H.R. 696, introduced by Mr. Morrison. I believe we have the departments involved in that legislation testifying today. I understand that they may have concerns with the bill. However, I would hope that we could take those concerns into account and perhaps move on to a mark-up of the legislation, early next year. Mr. Morrison will have more to say on that issue and his wishes in regards to moving that legislation.

Once again, thank you for calling this hearing. Judging from the witness list, I think we will hear from all sides of the irradiation issue and look forward to that.

Mr. BEDELL. Thank you very much, Mr. Roberts. Mr. Morrison.

OPENING STATEMENT OF HON. SID MORRISON, A REPRESENTATIVE IN CONGRESS FROM THE STATE OF WASHINGTON

Mr. MORRISON. Thank you, Mr. Chairman.

First, Mr. Chairman, I want to thank you and our ranking member, Mr. Roberts, for these hearings, for proceeding with this particular subject at this time. We had talked earlier in the year, and this came right after the farm bill, and you have certainly been true to your word.

Food irradiation has been around for many years. I have done a little reading back into the past to find in 1920 that its effects on insects were first noted. Most of the work, as Senator Harkin has indicated, came following World War II, but I think it is a technology whose time has now come, and its impact technically as postharvest treatment could be revolutionary. In fact, I think we could say, Mr. Chairman, that the subject of today's hearing could be the most significant development in food preservation and processing since the introduction of canning and freezing in the last century.

Irradiation kills undesirable biological elements that contaminate food without seriously eroding the food's nutritional value, retards spoilage, keeps food fresh and more natural tasting.

Mr. Chairman, I happen to have a couple of samples here of two hamburger buns made on the same day, one with irradiated flour, which was approved a number of years ago, and the one on this side, Mr. Roberts, is the one made with regular flour, and we can see this was about almost 2 years ago these were produced. So it does have some very highly desirable effects in a number of ways.

Its most immediate application is as a substitute for postharvest chemical pesticides. Besides being an attractive alternative to EDB and other fumigants, low doses of gamma radiation eliminate trichinosis in pork, stop the medfly in citrus fruits and, of particular interest to me, kill the codling moth in apples and cherries. Irradiation also destroys botulinum in red meats, poultry, and fish and extends the shelf life of highly perishable fresh fruits, vegetables, and grains. The process can prevent sprouting in potatoes and onions and delay the ripening of fruits such as bananas, mangoes, tomatoes, pears, and avocados. It has even been used to increase the juice yield of wine grapes.

Given all these potential applications, it is no wonder that food irradiation has attracted substantial attention from farmers, food processors, exporters, an infant irradiation industry, regulatory bodies, and the public.

I am pleased, Mr. Chairman, that the 1986 budget passed by this Congress, even with all the fiscal restraints on us, included $5 million under the category of food irradiation for the first time for the work that we believe should be done for demonstration of this technology, and I have just seen this morning a letter to the Department of Energy from the Appropriations Committee asking that the $5 million be extended to $7 million to cover the important products that are included.

A separate pork irradiation petition was approved by the Food and Drug Administration this past summer, and the agency is

here, and I believe they are on the threshold of approving low-dose food irradiation application for fresh fruits and vegetables.

So these are timely hearings and give us a chance both to look at irradiation as a process and consider legislative reforms. The subject of today's hearing is one of those proposed legislative reforms, H.R. 696, a bill introduced with the help of many of you back in January.

The legislation's aim is to advance the cause of consumer and commercial acceptance of food irradiation. Although I recognize that both USDA and FDA have reservations about some of the bill's provisions, I regard the bill as a rough cut, and I welcome and encourage refinements, particularly as they relate to the proposed Joint Operating Commission. I believe these hearings will lay the foundation for further consideration and ultimate approval of this bill.

I want to clarify one point, however, about a misunderstanding about the legislation. H.R. 696 does not undermine the current authority of the Food and Drug Administration to require labeling of irradiated foods. Mr. Chairman, I would ask at this point to submit for the record a letter from the Food and Drug Administration to Congressman Panetta in response to his question about labeling, in which they very clearly responded that they are not aware of any provisions of the legislation that affect Federal food irradiation labeling requirements.

Mr. BEDELL. Without objection, it will be entered in the record.

[The letter follows:]

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 31 1985

The Honorable Leon E. Panetta
House of Representatives
Washington, D.C. 20515

Dear Mr. Panetta:

This is in response to your letter of September 12 to Commissioner Young concerning the potential impact of H.R. 696, the "Federal Food Irradiation Development and Control Act of 1985," on food irradiation labeling requirements. This letter also confirms information exchanged on October 22 between Ms. Liz Turner of your staff and Dr. George Pauli of our Center for Food Safety and Applied Nutrition. You asked two questions. Our responses are as follows:

Question #1: Outline current food irradiation labeling requirements and implementation measures. In addition, please advise me as to whether these food irradiation labeling requirements are strictly adhered to.

Answer: The current labeling requirements for foods treated with ionizing radiation are found in Title 21, Code of Federal Regulations, sections 179.22 and 179.24 (copy enclosed). All labels and labeling must bear the statement "Treated with ionizing radiation" on retail packages and "Treated with ionizing radiation-do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipment. In any of these statements, the word "ionizing" may be replaced by "gamma" or "electron" as appropriate.

FDA has interpreted these requirements to apply only to foods directly irradiated, not to ingredients that may have been previously irradiated, such as spices, but are then added to a food which has not been irradiated.

Last year FDA proposed additional regulations for using ionizing radiation for treating foods. 49 Federal Register, 5714; February 14, 1984. The proposal also invited public comment on labeling issues. The Agency is currently reviewing approximately 5,000 comments that were received in the rulemaking proceeding.

The amount of food irradiated appears to be small, and consists primarily of spices and seasonings used as ingredients in other foods. We are unaware of any commercial irradiation of food for retail sale. Therefore, the labeling issue has not yet become significant from a practical regulatory standpoint. We have not had the occasion to take regulatory action involving irradiated food for labeling reasons.

Question #2: Evaluate and identify how H.R. 696 may affect food irradiation labeling requirements.

Answer: We are not aware of any provisions in H.R. 696 that would affect federal food irradiation labeling requirements. However, section 4 of H.R. 696 contains a specific preemption provision that would prevent a state from imposing additional or different labeling requirements on irradiated foods.

The Agency's labeling authority is generally set forth at sections 403 and 409 of the Federal Food, Drug, and Cosmetic Act (21 USC §§343 and 348). H.R. 696 would not change these sections relative to food irradiation labeling requirements except to add the words "or process" after the words "the additive" in section 409(c)(3)(B). Thus we believe this bill would not substantively change federal food irradiation labeling requirements.

I hope this information is helpful to you. If we can be of further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
Title 21 CFR, sections 179.22 and 179.24

Mr. MORRISON. In fact, the issue of labeling, of course, has been kicked around quite a little, and I am sure the number of months that the Food and Drug Administration has taken in moving forward their proposal for low-level treatments probably have revolved around the question of labeling and what should be done, and it is my feeling that they probably will include some sort of a reasonable labeling provision.

We have a number of witnesses today, and I commend you and your staff, Mr. Chairman, for putting together all the groups that are here. I look forward to hearing all of these views expressed by the variety of witnesses. While I suspect there will be some disagreements, I believe we all share a common objective to insure that we provide the consumer with safe and wholesome foods.

Mr. Chairman, I have one other item I would like to submit for the record, a handout of studies on the safety of food irradiation, which will react to some of the thoughts that are going to be expressed, I am sure, today since we have heard them before. I believe that should be part of the record as well.

Mr. BEDELL. Without objection, it will be entered in the record with your prepared statement.

Mr. MORRISON. I thank you for this opportunity to make this opening statement.

[The prepared statement of Mr. Morrison follows:]

OPENING STATEMENT OF THE HONORABLE SID MORRISON ON FOOD IRRADIATION

THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE

NOVEMBER 18, 1985

GOOD MORNING, MR. CHAIRMAN. FIRST, I COMMEND YOU FOR HOLDING THESE IMPORTANT HEARINGS. I HAVE TAKEN A VERY ACTIVE INTEREST IN FOOD IRRADIATION, AND I APPRECIATE THIS OPPORTUNITY TO DISCUSS FULLY, IN AN OPEN HEARING, THE FOOD IRRADIATION PRESERVATION PROCESS.

FOOD IRRADIATION IS A TECHNOLOGY WHOSE TIME HAS COME. ITS IMPACT AS A POST-HARVEST TREATMENT COULD BE REVOLUTIONARY. IN FACT, FOOD IRRADIATION COULD BE THE MOST SIGNIFICANT DEVELOPMENT IN FOOD PRESERVATION AND PROCESSING SINCE THE INTRODUCTION OF CANNING AND FREEZING IN THE LAST CENTURY.

FOOD IRRADIATION KILLS UNDERSIRABLE BIOLOGICAL ELEMENTS THAT CONTAMINATE FOOD WITHOUT SERIOUSLY ERODING THE FOOD'S NUTRITIONAL VALUE. IT RETARDS SPOILAGE AND KEEPS FOOD FRESH AND MORE NATURAL TASTING. ITS MOST IMMEDIATE APPLICATION IS AS A SUBSTITUTE FOR POST-HARVEST CHEMICAL PESTICIDES. BESIDES BEING AN ATTRACTIVE ALTERNATIVE TO EDB AND OTHER FUMIGANTS, LOW DOSES OF GAMMA RADIATION ELIMINATE TRICHINOSIS IN PORK, STOP THE MEDFLY IN CITRUS FRUITS AND, OF PARTICULAR INTEREST TO ME, KILL THE CODLING MOTH IN APPLES AND CHERRIES. IRRADIATION ALSO DESTROYS BOTULINUM AND SALMONELLA IN RED

MEATS, POULTRY, AND FISH AND EXTENDS THE SHELF LIFE OF HIGHLY PERISHABLE FRESH FRUITS, VEGETABLES, AND GRAINS. THE PROCESS CAN PREVENT SPROUTING IN POTATOES AND ONIONS AND DELAY THE RIPENING OF FRUITS SUCH AS BANANAS, MANGOES, TOMATOES, PEARS, AND AVOCADOS. IT HAS EVEN BEEN USED TO INCREASE THE JUICE YIELD OF WINE GRAPES.

GIVEN ALL THESE POTENTIAL APPLICATIONS, IT'S NO WONDER THAT FOOD IRRADIATION HAS ATTRACTED SUBSTANTIAL ATTENTION FROM FARMERS, FOOD PROCESSORS, EXPORTERS, AN INFANT IRRADIATION INDUSTRY, REGULATORY BODIES, AND THE PUBLIC. THE FDA IS ON THE THRESHOLD OF APPROVING LOW-DOSE FOOD IRRADIATION APPLICATIONS FOR FRESH FRUIT AND VEGETABLES. A SEPARATE PORK IRRADIATION PETITION WAS APPROVED BY FDA THIS PAST SUMMER. THESE TIMELY HEARINGS, GIVEN ALL THIS INTEREST, GRANT US AN OPPORTUNITY TO REVIEW THE PROS AND CONS OF FOOD IRRADIATION AND CONSIDER POTENTIAL LEGISLATIVE REFORMS.

ONE OF THESE LEGISLATIVE APPROACHES IS H.R. 696, A BILL I INTRODUCED BACK IN JANUARY. I'M PLEASED THAT A MAJORITY OF THIS SUBCOMMITTEE, INCLUDING THE DISTINGUISHED CHAIRMAN AND RANKING REPUBLICAN MEMBER, HAVE SPONSORED THIS BILL. THE LEGISLATION'S AIM IS TO ADVANCE THE CAUSE OF CONSUMER AND COMMERCIAL ACCEPTANCE OF FOOD IRRADIATION. ALTHOUGH I RECOGNIZE THAT BOTH USDA AND FDA HAVE RESERVATIONS ABOUT SOME OF THE BILL'S PROVISIONS, I REGARD THE BILL AS A ROUGH CUT, AND I WELCOME AND ENCOURAGE REFINEMENTS, PARTICULARLY AS THEY RELATE TO THE PROPOSED JOINT OPERATING COMMISSION. I HOPE THESE HEARINGS WILL LAY THE FOUNDATION FOR FURTHER CONSIDERATION AND ULTIMATE APPROVAL OF THIS BILL.

I MUST CLARIFY NOW, HOWEVER, A MISUNDERSTANDING ABOUT MY PROPOSED LEGISLATION. H.R. 696 DOES NOT UNDERMINE THE CURRENT AUTHORITY OF THE

FOOD AND DRUG ADMINISTRATION TO REQUIRE LABELLING OF IRRADIATED FOODS. IT HAS NEVER BEEN MY INTENT TO BAN LABELLING. I BELIEVE THE CONSUMER HAS THE RIGHT TO KNOW IF THE FOOD HAS BEEN IRRADIATED, AND I AM TROUBLED BY CHARGES THAT MY BILL IS ANTI-LABELLING. THE BILL IS, IN FACT, LABEL NEUTRAL.

WE HAVE A BEVY OF WITNESSES TODAY REPRESENTING THE COMMODITY ASSOCIATIONS, THE SCIENTIFIC COMMUNITY, AND CONSUMER ACTIVIST ORGANIZATIONS. I LOOK FORWARD TO HEARING ALL THE VARIOUS VIEWS EXPRESSED BY THESE WITNESSES ON FOOD IRRADIATION. WHILE I SUSPECT THAT THERE WILL BE SOME DISAGREEMENTS, I BELIEVE WE ALL SHARE A COMMON OBJECTIVE: TO ENSURE THAT WE PROVIDE THE CONSUMER WITH SAFE AND WHOLESOME FOODS.

THANK YOU, MR. CHAIRMAN.

STUDIES ON THE SAFETY OF FOOD IRRADIATION

November 18, 1985

Those who question the safety and wholesomeness of food irradiation point to few studies. These anomalous studies fly in the face of the vast consensus of studies confirming the safety of food irradiation. These adverse studies used questionable methodology, have not been replicated, and have been discounted by peer reviews.

Specifically:

The Indian Study

A 1975 study in India alleged that a blood chromosome disorder (polyploidy) resulted in children who were eating irradiated wheat.

Responses:

- **Sample size was small.** Only 12 children were involved in the study. The sample size is too small to render statistically significant results.
- **The study was done on malnourished children.** Malnourished children are more vulnerable to this particular blood order to begin with.
- **Other studies are critical of the India methodology.** A 1978 study in the Journal of Nuclear Agricultural Biology concluded that the India study was "not designed well" and the results were "imprecise".
- **Other studies specifically refute this study.** The following five published studies reviewed the India study and refuted it:

Journal of Food and Cosmetic Toxicology 1976
Technical Report Series of the International Project in the Field of Food Irradiation 1977
Journal of Toxicology 1977 (letter)
Jounral of Food and Cosmetic Toxicology 1981
Joint WHO Expert Committee Report 1976

Russian Studies

Two 1970 Russian studies claimed that kidney disorder and other abnormalities occurred in white rats who were fed irradiated meat and fish.

Respones:

- **The studies' methodology was questionable.** The irradiated sample was stored for 2 months at relatively high temperatures. The control sample (non-irradiated food) was frozen.

- **A peer review questioned the Russian studies.** The Natick laboratories commissioned a review in the early 1970's. The conclusion of the review was that the Russian studies did not meet modern diet standards and that the results were not statistically significant.

- **The Joint Expert Committee specifically refuted the studies.** The International FAO and WHO Expert Committee concluded that the work of the Russian studies was "so poorly done that it should never have been reported in the literature". (Journal of Industrial Irradiation Technology 1985)

- **Subsequent Russian studies support the safety of food irradiation.** Four separate studies reported in the Russian Journal of Proprosy Pitaniya (1973, 1977 and two in 1981) affirmed that food irradiation is safe and wholesome and that prior studies were not supportable.

Aflatoxin Studies

Some studies performed in India and the United States have concluded that food irradiation results in the creation of increased aflatoxin production.

Responses:

- **The India study's methodology was questionable.** A 1981 Journal of Food Science article criticized this study because the irradiated wheat was heat sterilized. It was the heat sterilization, not the irradiation, that caused the aflatoxin production.

- **Other studies refute the aflatoxin conclusion.** See Applegate and Chipley in Poultry Science, 1973; Bullerman, Barnhart, and Hartung in the Journal of Food Science, 1973; and Guilbot in Food Irradiation, 1970.

- **The adverse studies don't replicate actual use conditions.** In the leading United States aflatoxin study, the mold spores were irradiated in aqueous suspension, then inoculated into grain. Under proposed FDA regulations, however, grain with any mold present would be irradiated after harvest. Thus, concludes the FDA, "the study does not replicate actual use conditions". (49 Federal Register 5717, February 14, 1984)

Radiation Resistance of Bacteria Studies

Canadian laboratory studies reported in 1961 and 1963 were able to produce an increase in the radiation resistance of a bacterial strain. These studies raise the concern that food irradiation may create mutations of radiation resistant foods.

Responses:

- **These studies are not practical.** The foods were irradiated 84 times. After that many treatments of any process, a certain resistance would start to be seen. Foods in the commercial sector will not be irradiated 84 times.

- **Results are not unique.** Even with these multi-irradiations, no mutated radiation resistance was found to yield a greater resistance than naturally occurring organisms. (Journal of Industrial Irradiation Technology, 1985)

Mice Fed Irradiated Chicken Study

An American study reported in 1984, involving the feeding of radiation sterilized chicken to mice, resulted in questions requiring toxicological interpretation. This study is referred to as the Raltech study.

Responses:

- **The dose level was high.** The dose level in the Raltech study was about 5.9 Megarads, a dose 59 times higher than the dose level now being considered by FDA for approval. Even the supervisor of the Raltech study agrees that this high dose study only confirms the safety of low-dose food irradiation applications.

- **Peer Review dismisses the study.** At the FDA's request, the National Toxicology Program this past spring conducted a peer review of the Raltech study. The conclusion of the review: no pathological effects from food irradiation were found. The FDA futher concluded: "the NTP's Board of Scientific Counselors concluded that the available data did not allow the study [the Raltech study] to be categorized as demonstrating a carcinogenic response. The agency has reviewed all available animal feeding studies in its files and finds that no study, including the Raltech study, showed treatment-related effects that would preclude approving [low-dose food irradiation applications]." (50 Federal Register 24190, June 10, 1985)

Mr. BEDELL. Thank you, Mr. Morrison, and thank you for your leadership in this area.

Mr. Brown held hearings on this subject in the last Congress and has been very active on this issue. We appreciate all you have done as well, George.

We next will hear from the Department of Agriculture, from Don Houston, the Administrator, Food Safety and Inspection Service, U.S. Department of Agriculture.

STATEMENT OF DONALD L. HOUSTON, ADMINISTRATOR, FOOD SAFETY AND INSPECTION SERVICE, U.S. DEPARTMENT OF AGRICULTURE, ACCOMPANIED BY WILLIAM HELMS, ASSOCIATE DEPUTY ADMINISTRATOR, PLANT PROTECTION AND QUARANTINE, ANIMAL AND PLANT HEALTH INSPECTION SERVICE; HAROLD REUBEN, DEPUTY ASSISTANT GENERAL COUNSEL; AND TERRY B. KINNEY, ADMINISTRATOR, AGRICULTURAL RESEARCH SERVICE

Mr. HOUSTON. With me today is Mr. William Helms, Associate Director for Plant Protection and Quarantine for the Animal and Plant Health Inspection Service, Mr. Hal Reuben from our General Counsel's Office, and Dr. Terry Kinney, Administrator of the Agricultural Research Service.

Thank you for the opportunity to testify on H.R. 696, which provides for Federal coordination for continued development and commercialization of food irradiation through the establishment of a Joint Operating Commission for Food Irradiation in the Department of Agriculture.

Let me generalize by saying that we recommend sections 3 and 4 be amended to take into account the responsibilities of the Secretary in administering the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act. We oppose section 6 on the basis that coordinating mechanisms are already in place, and a new layer of authority is unnecessary.

Turning to research activities, USDA has conducted research on food irradiation for more than 30 years. That research has involved the use of low-dose irradiation of up to 100 kilorads as a quarantine treatment for insects in place of chemical fumigants and for the control of trichinae in pork; the use of medium doses of between 100 kilorads and 1 megarad for the control of microorganisms for pasteurization; and the use of high doses above 1 megarad for sterilizing foods.

On February 14, 1984, the Food and Drug Administration [FDA] issued a proposed rule to permit the use of food irradiation at doses of up to 100 kilorads for inhibiting the growth and maturation of fresh fruits and vegetables and for disinfesting foods of insects. The proposal would also permit the use of irradiation to disinfest spices of microbes at doses not to exceed 3 megarads, or 3,000 kilorads. We expect FDA to issue a final rule on the proposal soon.

With the loss of ethylene dibromide as a fumigant and the current lack of acceptable chemical alternatives, it is becoming more apparent that radiation treatment of certain commodities may play an increasingly important role in allowing their continued movement in national and international commerce. Accordingly,

USDA's Agricultural Research Service [ARS] has expanded its research program in anticipation of an FDA ruling. ARS is concentrating on selected fruits and determining the radiation dosage necessary to provide quarantine security.

Insect pests and commodities under investigation are the Caribbean fruit fly in mangoes, grapefruits, oranges and tangerines from Florida; the Mexican fruit fly in mangoes, grapefruits, oranges, and tangerines from Texas; the West Indian fruit fly in mangoes from Mexico; the codling moth in apples and walnuts from Washington and California; and the cherry fruit fly in cherries from Washington. We expect to complete these projects by the fall of 1987.

Results of the research can also be used to control pests on commodities from other areas, such as the Caribbean fruit fly in mangoes from Haiti and Puerto Rico or the Mexican fruit fly in mangoes from Central America.

Much of USDA's irradiation research has been with papayas. That work has shown that irradiation has definite advantages over chemical fumigation or vapor heat treatment of papayas because: One, it is much more efficient and can be a continuous process; two, it ensures complete disinfestation; three, unlike many fumigants, it leaves no residue on the fruit; four, it prolongs the shelf life of fruit by delaying ripening, unlike fumigation and vapor heat treatment, which tend to accelerate ripening; and, five, in the long run it would produce a cleaner environment because a smaller volume of pesticides could be applied to the preharvested fruit crop if irradiation were used for quarantine treatment.

Research on radiation treatment for the Mediterranean, oriental and melon fruit flies found in Hawaiian papaya was completed several years ago. We will begin studies of other commodities as soon as possible.

USDA research in medium-dose and high-dose food irradiation: Bacterial contamination of meat and meat products can be reduced at irradiation doses between 100 and 600 kilorads. Studies are underway to determine optimum exposure regimes for extending the shelf life of meat and poultry, reducing microbial spoilage, and reducing or eliminating food poisoning bacteria.

Sterilization of food with high doses of irradiation has been investigated for many years by the Department of Army and USDA. In 1980, the Army transferred to USDA its programs related to the irradiation of meats, including data generated from completed work. This data and the results of wholesomeness studies of precooked irradiated chicken were delivered to FDA on March 30, 1984. FDA indicated that it would review the data for its relevance to other proposed uses of irradiation and food preservation. Future USDA research will concentrate on low doses of irradiation studies for quarantine treatment, medium dose studies for determining the relative susceptibility of bacteria to irradiation and the effect of irradiation on food quality.

Thus far, USDA research suggests that irradiation could be successful as a commercial treatment to stop the spread of exotic pests. The Department believes that irradiation as a quarantine treatment has great potential for permitting the movement of several commodities in international and national commerce. Particularly attractive is its lack of potentially adverse effects on the envi-

ronment. If low-dose irradiation is approved for use on fruits and vegetables, USDA will move as rapidly as possible to establish treatment schedules. USDA's Animal and Plant Health Inspection Service [APHIS] would establish treatment schedules based on ARS research.

While we are prepared to move ahead quickly if FDA approves the use of low-dose irradiation on fruits and vegetables, an approved treatment schedule for papayas is the only one that USDA could implement immediately. More work is required for the treatment of apples and walnuts for codling moths and of citrus for various kinds of fruit flies. In addition, before irradiation is used on a large commercial scale, industry needs to be convinced that the process can work. While some in industry have already invested in developing irradiation treatment, demonstrations are needed to show even larger groups that irradiation is feasible as a quarrantine treatment.

Mr. Chairman, I know my time is up, but in about 2 minutes I can complete this testimony.

Mr. MORRISON. Mr. Chairman, I might ask Mr. Houston be given the extra time since he is making a presentation for several agencies at one time.

Mr. BEDELL. Is there objection? If not, you may proceed.

Mr. HOUSTON. USDA considers FDA's July 22 approval of irradiation of fresh pork another approach that FSIS, as a public health agency, may take in dealing with the risk of human trichinosis. Shortly after FDA's action, USDA received a petition from Radiation Technology of Rockaway, NJ, requesting FSIS approve the use of irradiation for the treatment of fresh pork. On the basis of that petition, FSIS began:

One, developing a final rule adding the irradiation of fresh pork to the list of food additives found in the Federal meat inspection regulations—although the rule will be final when published, it will provide for a public comment period after publication;

Two, developing interim guidelines relating to plant operating procedures, the safety and training of employees, sanitation, facilities, quality control programs, and labeling; and

Three, preparing a proposed rule that will outline our specific regulatory authority and the direction we propose to take in developing long-term procedures and policy relating to the regulation of irradiation. I want to emphasize that the final rule which is developed as a result of this phase of rulemaking may modify the interim guidelines.

A workable irradiation inspection program should be in place shortly after the first of the year. Under the guidelines, every irradiation plant will have to submit a quality control program to FSIS for approval before it may irradiate pork.

USDA inspectors will monitor critical control points identified in quality control programs to verify that the irradiation process is being applied correctly.

In addition to FSIS requirements concerning facilities, equipment and sanitation, irradiation facilities must comply with the requirements of certain other Federal agencies before a grant of inspection is issued. Other agencies are the Nuclear Regulatory Commission, the Occupational Safety and Health Administration and

the Environmental Protection Agency. USDA will work closely with these other Federal agencies.

Another important component of the interim guidelines will focus on wholesale and retail labeling of irradiated pork products. With regard to wholesale labeling, irradiated products in commercial distribution channels must be clearly labeled as irradiated. This labeling must be maintained at every stage of distribution to prevent the possible reirradiation of foods. For retail labeling, we will require that irradiated fresh products bear a label statement to that effect. Processed meat products, which are so-called second-generation foods, may contain various amounts of meat and other ingredients. Therefore, we are considering the need for processed products made from irradiated pork to bear a label statement that ingredients have indeed been irradiated. We are aware there may be a level of irradiated ingredients that would be so insignificant as to not require labeling.

Mr. Chairman, in closing let me say that in addition to developing methodology for use by agricultural industries, USDA's proper role in the development of a new technology includes ensuring that all safeguards have been identified for consumer protection and product quality. USDA will continue its research efforts and will continue to develop regulatory programs and provide technical information on irradiation to industry and consumers.

This completes USDA's testimony, Mr. Chairman. My colleagues and I will be happy to answer any questions you or other members may have.

[The prepared statement of Mr. Houston appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much.

Mr. Morrison.

Mr. MORRISON. Thank you.

Mr. Houston, I notice in your comments you have suggested amendments be offered so you bring the acts which you administer, meat products, poultry products, egg products, so they too would reference a change as far as irradiation we are proposing as far as the Food and Drug Administration is concerned. Is that accurate?

Mr. HOUSTON. That is accurate, yes, sir.

Mr. MORRISON. Your feeling, while those acts reference back to section 409(b), which we specifically reference in the bill H.R. 696 that is not adequate and you want it very definitely clarified that you continue to have authority over these processed products?

Mr. HOUSTON. Yes; we look upon it as conforming language.

Mr. MORRISON. I just want to comment, Mr. Chairman, that we have absolutely no opposition at all to the request made by USDA. These are important safety programs which they administer and there was absolutely no intent at all to short circuit any of their processes.

Mr. Chairman, thank you.

Mr. BEDELL. Mr. Brown.

Mr. BROWN. I don't think I have any questions of this witness, Mr. Chairman.

Mr. BEDELL. Mr. Morrison, is it section 3 or 4 where they wanted the change made?

Mr. MORRISON. Mr. Chairman, we thought that had been adequately handled but where there is any concern, as Mr. Houston expressed, we certainly would be willing to make the modifications that have been proposed.

Mr. BEDELL. Was that section 3 or 4? He objected to changes in both sections 3 and 4, is that right?

Mr. HOUSTON. Yes, sir; sections 3 and 4.

Mr. BEDELL. Does this take care of both of those concerns?

Mr. Houston, can you tell us?

Mr. HOUSTON. Yes; If we would amend sections 3 and 4 as we have described in the testimony and with the language that we will make available to the committee that will solve the problem.

Mr. BEDELL. No; my question is, since Mr. Morrison has agreed with you that the effort is not to take away the authority of the Department, do sections 3 and 4 both address that issue or do they address different issues?

Mr. HOUSTON. They address that issue.

Mr. BEDELL. You also oppose section 6. You say it is not needed. Your testimony says the Office of Science and Technology Policy is considering a Commission on Food Irradiation. As I understand it you believe we don't need section 6 because the Office of Science and Technology Policy is considering that. I, for one, think considering is quite different from instituting. Would you feel we should change that to say it will be there until such time as they institute such a commission or do you feel it ought to be deleted regardless?

Mr. HOUSTON. We believe it should be deleted regardless. We are concerned that such a coordinating mechanism mandated by law takes away a great deal of flexiblity that may be needed in the future. Irradiation is an evolutionary process at this point, and I think we need to remain flexible. I don't think we need to add mechanisms that are going to create more costs at this time and from what we have seen, there simply isn't the need for this kind of mechanism.

Mr. MORRISON. Mr. Chairman, if you will yield to me, I would like to comment only on that so we bring this issue completely out in the open. As I understand, there is proposed in the White House a coordinated group under Mr. Keyworth as the Science Adviser to the President. That is just fine. The problem is that I am not so sure it will exist from administration to administration and that was the reason for our thinking on a joint operating commission that gets together for meetings on a regular basis the people from the various agencies that have been involved in food irradiation. So, that was our thinking. Again though we are choosing to be flexible on this subject.

We don't want to create any sort of bureaucratic monster, but we did include consumer representatives as well as the representative from each of the agencies, feeling that that might have the ability to move through from administration to administration as opposed to waiting for something that might well be established by this current administration.

Mr. BEDELL. I think probably the chairman should be candid. My experience with Mr. Keyworth is such that I wouldn't give him anything. I have had very bad experiences with Mr. Keyworth in regard to the Small Business Administration and his absolute re-

fusal to obey the law. I think we ought to get it right out in the open that he refused to come before one of our subcommittees in the Small Business Committee. He is not conforming with the law as the Congress passed it in regard to a small business issue.

Mr. Evans, do you have any questions?

Mr. EVANS of Iowa. None.

Mr. BEDELL. Who pays for the supervision of this process? Do the taxpayers pay for that or is there a charge by those processors?

Mr. HOUSTON. No, sir. This would operate under the Federal Meat and Poultry Inspection Program, which is funded through the appropriations process with the exception of overtime payments which the industry pays. Our annual appropriations is in the neighborhood of $365 million a year and we collect an additional $30 to $32 million a year in overtime payments from the industry.

Mr. BEDELL. Any further questions?

Mr. Roberts.

Mr. ROBERTS. I am sorry for being absent, Mr. Chairman. Are we in the business of having questions for the whole panel now or is this just after this——

Mr. BEDELL. This is the whole panel.

Mr. ROBERTS. Dr. Kinney, when we had testimony last May we were talking about some plan which in regard to apples, walnuts, I think the fruit fly in regard to grapefruit, Mexican fruit fly in regard to grapefruit and I was wondering if you could give us a very brief update on those activities and if you are conducting any further research into the use of this process on stored grain?

I might as well toss in the kitchen sink here as well. You indicated at that time you were redirecting funds toward more research. Could you give us an update with those numbers?

Mr. KINNEY. Mr. Roberts, I would first of all, I would like to submit a complete summary for the record, but I have here this morning Dr. Jane Robens, who is on our National Program Staff and she could give us a more detailed brief summary of what we are doing now. I can say that we have expanded and continued our research on irradiation, including traditional work on fruits.

Mr. ROBERTS. In the interest of time, Dr. Kinney, why don't we move on except that I would like to have submitted to the subcommittee where we are in regard to the planned research at that time and now it has been some time since we have had that hearing. I am particularly interested in the use in regard to stored grain which is obvious, being from my county.

[The information follows:]

Dr. KINNEY. Research on use of radiation for control of insects on/in grain was completed many years ago and approved for commercial use by FDA in the 60's. Therefore, we shifted our emphasis to fruits. The research for the melon fly, and the Mediterranean and oriental fruit flies in Hawaiian papaya is complete. Currently, we are investing $654,400 and 11 scientists for use of radiation as a quarantine treatment method. The locations where research are being conducted, and the commodities and pest species involved are as follows: Miami, Florida—Caribbean fruit fly in grapefruits, oranges, and tangerines; Weslaco, Texas—Mexican fruit fly in mangoes, oranges, tangerines, and grapefruits; Yakima, Washington—codling moth in apples, and cherry fruit fly in cherries; and Fresno, California—codling moth in walnuts.

Mr. ROBERTS. I am wondering also if the Department has taken on the issue of labeling of food items. If anybody would like to respond to that?

Mr. HOUSTON. Mr. Roberts, as I mentioned in the testimony, we will have a pork irradiation program on-line shortly after the first of the year. As part of our interim guidelines, we will require labeling of the products involved. This includes those products that are moving in wholesale as well as products that appear at the retail level; both will have to carry some kind of mention that they have indeed been irradiated. We are flexible in the terminology being required at this time. For example, it might be labeled "treated to destroy trichinae" or "irradiated" or "treated with irradiation." There are a number of possibilities that could be used. We have these as part of our interim guidelines, and obviously as long term policy is develped through the rulemaking process, there could be some changes. But that is our position at this time.

Mr. ROBERTS. I am particularly interested in the consumer reaction to labeling and to this process in regard to consumer acceptance. Have you done any surveys on consumer reaction to labeling? Has that been considered?

Mr. HOUSTON. I don't recall any surveys off hand. I have looked at some reports which would indicate that there is growing consumer acceptance for the use of irradiation as an alternative to chemical treatment. There are some surveys conducted by the Good Housekeeping Institute which show this. That being the case, we believe that if we are going to continue to have that acceptance, consumers need to know whether the foods they purchase have been irradiated. I think if we do otherwise we may raise feelings of distrust and suspicion about the use of irradiation.

I believe we are at a crossroads. It looks to me as if pork is going to be the first major commodity on the market that has been irradiated, and I think if we handle it poorly we could set back the whole process for quite some time. I suggest we be open and honest, and tell consumers what is occurring and give them a choice.

Mr. ROBERTS. I certainly appreciate your comment in that regard. I am afraid if we don't go through the process of labeling, whether it be—I have a suggestion here, ionized for your protection is one.

We have international symbol here, which is another one. If we don't do this right with full public disclosure and acceptance, I think the issue then becomes the labeling and not the process, and that would be most unfortunate.

I thank the chairman.

Mr. BEDELL. Mr. Houston, is there a problem if you reirradiate some of these things? Do you have any indication that is a problem?

Mr. HOUSTON. The Food and Drug Administration has set limits regarding irradiation of pork for destroying trichinosis. It is between 30 and a 100 kilorads. Obviously, if we reirradiate foods then we go past those standards which FDA has set, so we want to be sure that doesn't occur again.

Mr. BEDELL. What problems does that cause?

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Mr. HOUSTON. Well, I would defer to the FDA, since they made the safety decision, but as you reirradiate the dosage level increases and we then become unsure about the safety data supporting irradiation at those levels. It is for that reason they have put an upper limit on allowable dosage levels.

Mr. BEDELL. Have there been tests at the upper levels?

Mr. HOUSTON. Yes. I would prefer to defer to FDA, who will follow me, as to the evaluations they made in making safety determinations.

Mr. BEDELL. OK.

Any further questions?

If not, we appreciate your testimony very much. We may be contacting you with further questions.

STATEMENT OF FRANK E. YOUNG, M.D., PH.D., COMMISSIONER, FOOD AND DRUG ADMINISTRATION, PUBLIC HEALTH SERVICE, DEPARTMENT OF HEALTH AND HUMAN SERVICES, ACCOMPANIED BY SANFORD A. MILLER, PH.D., DIRECTOR, CENTER FOR FOOD SAFETY AND APPLIED NUTRITION; THOMAS SCARLETT, CHIEF COUNSEL; AND MR. NORRIS, DEPUTY COMMISSIONER

Dr. YOUNG. I would like to introduce on my left, Dr. Sanford Miller who is head of the Center for Food Safety and Applied Nutrition; Mr. Scarlett, the General Counsel; and Mr. Norris, my Deputy Commissioner.

We have studied the process of food irradition for many years beginning with 1963, when FDA approved the gamma irradiation for the conserving of canned bacon.

I have listed, in appendix B of my prepared testimony, a variety of actions. Suffice it to say, since 1979, we established a committee to look at the safety of irradiated foods, and are convinced at this time that under the 100 kilorad level that the process is safe and is a very important consideration for a substitute for some of the chemical pesticides at this time.

We have, accordingly, in 1981, offered an opportunity for the use of irradiation for insect infestation. In 1983, we approved the gamma irradiation for microbial decontamination of specific species and vegetables, and in 1984, we proposed a rule in the Federal Register in regards to sprout inhibition and shelf life extension for fresh fruits and vegetables.

In 1984, also, we amended the Food Additive Regulation to provide for the safe use of a source of gamma irradiation to control insect infestation and, as was mentioned, in 1985, also, we looked at the amending for the Food Additive Regulations to permit the gamma treatment of pork to control trichinella spiralis infection.

All of this was related to our assumption based on our scientific evidence that that was a safe process.

We appreciate the opportunity to comment on H.R. 696, and with the exception of some technical issues that were raised and some concern as addressed in my testimony to be sure that we have the continued authority to deal with this regulation, we feel that this is a bill that we would not object to at all.

We do feel, however, that the Joint Operating Commission is a commission that is not as effective at this time for three major reasons.

First, we feel that the flexibility is an important point.

Second, we feel that at this time of diminishing economic resource for the Federal Government that this would add an undue burden in regard to the cost of this particular Commission.

And third, we feel that it would be appropriate to maintain the flexibility that can be not just through the fix-it type committee through OSTP, but other mechanisms in which we could work together.

I have been pleased at the very close relationship between USDA and FDA as we have explored this. We have worked hand in hand and we do not feel an additional commission, respectfully, would substantially improve that cooperation.

Mr. Chairman, in view of the number of panels, I will cease my informal comments here and be delighted to answer any questions that I can.

[The prepared statement of Dr. Young appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much. Dr. Young.

Mr. Roberts.

Mr. ROBERTS. Yes. Thank you, Mr. Chairman.

Dr. Young, what is the FDA's policy on the labeling of this process?

Dr. YOUNG. We are currently determining what is the best way to go forward on labeling it. In the view of some who feel this process is a safe process, one could argue that labeling isn't necessary at all.

In fact, if one looks back, historically, when we began to preserve food with salting and then moved to various cooking and finally canning, we recognized these are processes that modify food for stages of preservation.

Those who feel this is a completely safe type of treatment wonder whether we need any specific labeling at all.

On the other hand, as you so clearly articulated, there is a concern as to whether or not we should have labeling so that consumers would fully know that this is an irradiated product.

Irradiation does not leave any residue at the 100 kilorads that we are treating this with. To our knowledge, there is no unsafe change in the food, but there is the issue of should consumers know what the process was.

At the very moment, we are trying to decide what is our appropriate policy.

Mr. ROBERTS. Would it be appropriate, in your opinion, to use the international symbol for this process? I think you have that proposed in your regulations.

Is that not correct?

Dr. YOUNG. That is correct. It is one of the items that we are considering, and if one did choose to label that would clearly be an option.

Symbols do provide a mechanism whereby we can clearly indicate to the public the type of process, but at the moment, until we determine whether or not the labeling would be appropriate, it is

hard to know whether the symbol would be better than any particular words as our colleagues in agriculture are using.

Mr. ROBERTS. I have a comment from one of the industry publications that says that you are maintaining that the use of a logo in this country for a minimum of 2 years is necessary before you can consider allowing that to replace any statement like the one I am suggesting, "Ionized for your protection."

Do you feel that a 2-year period is necessary in terms of the lead in? It is my understanding this is a pretty well accepted international symbol.

Is it such in this country we are just not familiar with it, and that would take us 2 years to get to that place or what?

Dr. YOUNG. The symbol has not yet been decided on internationally.

It is used in the Netherlands and South Africa most extensively and the Codex Alimentarius is beginning to consider whether an international logo could be given.

But until we determine whether or not labeling, per se, is recommended, we had considered various options so that the logo could be identified. But it has clearly not been established yet as an international norm.

Mr. ROBERTS. It has been standard in my family. This looks like a Pac Man kind of thing. I am not too sure what that means.

Dr. YOUNG. It is alleged to be a tulip.

Mr. ROBERTS. We will tiptoe through that subject here. No hissing here, please.

No more questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Dr. Young, just on my behalf personally, I want to thank you for the leadership of the Food and Drug Administration in this food irradiation area.

We patiently, sometimes impatiently, wait for the regulations to be finalized. As I understand, you are proceeding with the 100 kilorad limit, and is it true that that is reflected in countries around the world that have used the World Health Organization recommendations that your level is only one-tenth of the level approved in other parts of the world?

Dr. YOUNG. The FDA has, over the years, been a conservative regulatory agency, and thus we feel that there is a layer of safety at the level that we are recommending and did not find any undue risk that we could identify at all from the 100 kilorad level, and thus, it is below what has been used in some of the 21 countries that have approved this process for some particular foods to date.

Mr. MORRISON. As I recall from reading the World Health information, that they didn't find any undue risk at 10 times the level of treatment you are proposing.

Dr. YOUNG. There is no question that at higher levels others have thought that there was no particular risk as well.

Mr. MORRISON. Is this perhaps an effort by the Food and Drug Administration to be absolutely certain that what you are proposing is in the best interest of consumers?

Dr. YOUNG. Yes, it is.

We feel at this point at 100 kilorads, it would be no way in which there would be substantial modification of the food products and also would be very difficult at 100 kilorads to detect any changes.

It is one of the reasons that we chose this. It would be very hard to design experimental models, because the change is so infinitesimally small.

Dr. Miller, would you like to comment on this, please?

Dr. MILLER. Yes. The problem was and is that the data base on which the Joint Committee for Research depended, in our opinion, had some questions concerning the studies that were used.

We would agree that, on the whole, the pattern of studies indicate no problem even at that level.

But in an effort to be, as I say, ultracautious in this regard, we have decided we would like to proceed at the levels above 100 kilorads in an orderly fashion.

We will proceed one by one, rather than trying to reach a generic conclusion, and for the moment, for example, we are looking at some data concerning the use of levels above 100 kilorad to prevent salmonellosis in chicken, and we decided to take that route in order to avoid any of the debate over the quality of the data base that led to that original one megarad dose.

You are quite right. We are being very, very cautious in taking each step as it comes.

In conclusion, for 100 kilorads, we are convinced that generically, that is a safe dose.

Mr. MORRISON. In essence, you are establishing that level below which you will not have to do a tremendous review.

Dr. MILLER. That is correct.

Mr. MORRISON. However, you will consider petitions—as you have in the past—for treatments above that level as we understand better some of the commercial implications of higher levels of treatment.

Dr. MILLER. Exactly. We have tried to encourage the industry to come ahead with petitions on individual food items providing the appropriate data and indeed, in most cases, have laid out what kinds of additional studies we would need in order to fill in what we think the holes were for particular products.

In the cases of chicken, we have indicated certain studies which we think need to be done, and in other products, other studies, as well.

It is a question of being cautious rather than knowing something is unsafe, and we would rather be convinced it is safe.

Those are two different things.

Mr. MORRISON. Thank you.

Thank you very much, Mr. Chairman.

Mr. BEDELL. Mr. Brown.

Mr. BROWN. No questions.

Mr. BEDELL. Mr. Evans.

Mr. EVANS of Iowa. Thank you, Mr. Chairman.

I would certainly agree that the U.S. Government has been very conservative and deliberate in its considerations on acceptability of this practice.

I had the privilege of serving on the staff of the Atomic Energy Commission hearing here in Washington, DC, almost exactly 30

years ago, and the gentleman who had his desk next to mine was the Project Officer for Food Irradiation at that time, and he also had his desk drawer full of pork chops and steaks that were packaged in plastic and did not need refrigeration, and I stayed there for several years, and as I remember, he had the same steaks and pork chops in his desk drawer, unspoiled, at the end of that time as he did when they were put in there.

It would seem to me that 30 years is a very adequate time to determine the acceptability of some practice of this sort.

Specifically, I am curious about the dosage rate, and I would agree with you that 100 kilorads of gamma radiation would be exceedingly safe, but I am wondering, on some of these projects, at what level of gamma radiation dosage can any residual effects begin to be detected?

What I am getting at is how do you know it was limited to 100 kilorads, and at what point does it begin to show up in terms of examining a product to determine if that level has been exceeded?

Dr. YOUNG. This is a very difficult question, and one of the reasons that we deliberately went on a conservative approach to establish a level of safety, and then go on a case-by-case basis, is that it is hard to determine the additional levels. Those are done by long-term animal feeding studies and analysis of nutrients. Dr. Miller can provide some additional information on that, but basically it is on a case-by-case basis by which we look at these, using animal-feeding studies and an analysis of nutrients.

Mr. EVANS of Iowa. But in terms of physical characteristics of the product, am I correct it would require much more massive doses before there is any detectable change in the nature of the product with any scientific instrumentation or examination processes that we have at the present time?

Dr. MILLER. Right. Even at the high doses which are being considered for the purposes of sterilization, which are in the order of magnitude of 2 and 3 megarads and above, even then there is no induced radio-activity in the product, as we all know.

In terms of physical changes, a lot depends on the condition under which the food is irradiated, but then physical changes occur in thermal processing too. Canned green beans certainly don't taste the same as fresh ones, and pasteurized milk doesn't taste the same as raw milk, but it so happens that with the 100 kilorad level and below, it results in a product which is very little changed; in fact, so much so, sir, that we have great difficulty in distinguishing such products. In fact, we usually can't tell at all when these products have been irradiated.

Mr. EVANS of Iowa. Which is one of the reasons you want to put a sign on it?

Dr. MILLER. Which is one of the reasons we want to put a sign on it. We have inspectional authority in our proposal, and more than that, we have said again and again that an area of research that is absolutely required is post-irradiation dosimetry. How can we in fact detect the fact that the products have been irradiated in order to prevent let's say foreign products from coming in that are irradiated or not in plants we can't inspect?

Mr. EVANS of Iowa. And claiming that they are?

Dr. MILLER. That is right, exactly.

Mr. EVANS of Iowa. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Chairman. Mr. Gunderson.

Mr. GUNDERSON. I have only one question as to the caution that the Government has taken. You have heard that certain people have alleged that the approval of the pork irradiation was rushed through. Do you want to comment about that?

Dr. MILLER. It depends upon what kind of cosmic view you have of things. I suppose the period of time in which we looked at the pork irradiation proposal in detail was relatively short compared to the way we looked at everything else, but pork irradiation and the irradiation of any food have basically the same set of criteria that one looks at. A great deal of that work had already been done at the time we went ahead and looked at the product.

We had looked at the irradiation of pork very early; in fact all the way through pork was one of the products with which we were concerned. I don't think we rushed through it at all. I think there are some who would say we have taken too long, but I think so far as I am concerned it has just been the right time.

Dr. YOUNG. I would just add as Commissioner that the Center has particularly been vigorous in looking at this. The reason that I asked Dr. Miller to comment on this is his extensive examination over the years of his leadership in the Center on the safety of irradiation and I would agree, looking at this from the Commissioner's office, that there has been a prudent analysis not only of this particular action that we are looking at on fresh fruits and vegetables, but also on the more extensive examination of what should be done on the irradiation of pork.

Dr. MILLER. One further point. The levels we approved are within that 100 kilorad level which we on both the basis of experimental data on the one hand and theoretical analysis of the worst possible case situation—making assumptions about the maximum amount of unknown products that might be produced and the maximum toxicity, carcinogenesis if you will, that might be associated with these products—have come to the conclusion that the amounts which are produced under those circumstances are so small as to be insignificant, even assuming the worst possible cases for their toxicity.

And so the question with pork was not really a question so much of its safety. On that we were pretty well convinced. It was other issues, concerning dose penetration and how it is going to be done, and so on, that had to be considered as we went ahead with this. I don't think we were hasty in reviewing this problem.

Dr. YOUNG. I would also like to add, if I could, please, sir, that as a physician there has been interest in looking at food irradiation not in these doses that we are looking at here at very low levels but at higher doses for preparation of food products for individuals who are immunocompromised.

This study has been going on for a number of years, and I would like to submit for the record some of the correspondence that we have, because in this case of the compromised host, there is an advantage that can be used through sterilization at high levels of food products, and thus we are considering the full range on a case-by-case basis, but we should not overlook the medical issues that may be important in this process as well.

Mr. BEDELL. Without objection, those letters will be introduced or held in the subcommittee files.

Mr. GUNDERSON. Do you gentlemen suggest by the general nature of research that affects not only pork but all food areas that once you have made the initial approvals that we can see a whole series of approvals in relation to irradiation?

Dr. YOUNG. We would predict at this moment that there would be an increased use of irradiation for food products. We established this level at 100 kilorads because we feel that this is a level which is, to the best of our scientific analysis, safe. We would anticipate looking at a case-by-case level beyond that, and in other processes, but certainly as Dr. Miller has focused, the pork irradiation is within that 100 kilorad level that we looked at and consider as safe.

There are other uses that have been particularly recommended for spices that exceed the 100 kilorad level, and there may be others, once the industry, the public and the scientific community gets more experience with this particular form of preservation.

Dr. MILLER. Just to expand a little bit on the statement, the answer to your question directly is yes, because basically the chemistry is the same, and we know a great deal about radiation chemistry, which we have learned over the past 100 years. Our chemists could then predict whether or not there would be anything special about a particular product based on either water content, composition, and so on, and then we need to know whether we should have any special studies done.

At this sub-100 kilorad level thus far, for most products, safety issues have been established. Finally, the question that comes up only is: is it effective for whatever you want to use it for? And that is another question. It is a technological question that has to be answered rather than a safety question.

Mr. GUNDERSON. Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Roberts, did you have another question?

Mr. ROBERTS. Yes, Mr. Chairman.

Along the same line that my colleague from Wisconsin has raised one issue I think in conjunction with the criticism that we have heard in regard to the pork issue is that in that same story one other issue that was raised was the chemical changes that food undergoes in this process, and I am wondering—and I suppose this question should have been asked of the USDA—I am wondering, is the Department or are you, is the consortium, if you will, are you doing any research? Just how extensive is the research in terms of scientific knowledge in regard to the area of chemical changes in food that has gone through this process?

Dr. YOUNG. The Department of Agriculture has been focusing more on the research aspects than FDA has. The only nutrients that have been looked at extensively are thiamin and the question of whether there might be some change there. But the levels that we are using in our approval process are so low that we do not consider at this moment any substantial nutrient changes.

But, Dr. Miller, would you like to add anything further to that?

Dr. MILLER. USDA is doing some extensive work on nutrient changes. The standard we use is that the change in nutrients should be no different, no greater than that produced by any other

process, and from data so far for things like pork, it just suggests that it doesn't happen, losses are no greater. However, further work is going on in that area, and it is a question we raise with every petitioner, because it is one of the areas of question we need to deal with.

USDA is also I think looking into some of the chemical changes associated with chicken for the use of irradiation for control of salmonellosis. And if the industry is going to want levels above 100 kilorads in petitions then we are going to want substantial data in some cases on the chemical changes taking place. Yes, we keep on exploring that not only for the individual products, but just to increase the whole data base, so that the more we know the less we need for the future.

Mr. ROBERTS. Thank you.

Mr. BEDELL. Dr. Young, on page 3 of your testimony you say, "Concerns are twofold. First, there is concern for the possible long-term toxicological effects of the radiolytic products formed in foods as a consequence of this irradiation process, that the concern is proportionally to absorb those significantly in food in one's diet." Is that to say that the concern is that irradiation might cause some effects on the food that people eat that could then give them problems?

Dr. YOUNG. Yes, that was the original concern that was raised when the process was looked at many years ago. In the use of ionizing irradiation there is a possibility from the variety of sources to change particular chemicals. Part of my past expertise was working as a professor of irradiation biology and biophysics, in which we looked at radiant energy in regard to cell biology, and the focus that one looks at is what does this added energy do to proteins, carbohydrates, and lipids within cells. At the level which we have chosen to approve this process, 100 kilorads, there is essentially no significant radiolytic products that we could detect that would be harmful.

In the case of the very high doses used for sterilization, as I mentioned, for patients that were receiving treatment for immunocompromised status, there some of the irradiated food was up to 25 percent of the diet and over a 10-year period of time there were no reported adverse reactions there, but in prudent chemical analysis, scientists would look to determine at various levels whether changes existed within the foods themselves. At the level that we are recommending the first baseline of approval, there does not seem to be any problem with radiolytic——

Mr. BEDELL. At the sterilization level can you detect changes?

Dr. YOUNG. At the sterilization level we would be much more able to detect these changes over a period of time.

Mr. BEDELL. Can you detect changes in food that is irradiated at the sterilization level? Do you?

Dr. YOUNG. I would predict that we would be able to see some changes in some of the thiamin residues. This has not been analyzed carefully enough to my knowledge to give a detailed analysis of each of the nutrients.

Dr. Miller, could you provide any more detail?

Dr. MILLER. You do find changes in these products that are not uniform from product-to-product, so that you can't say, well, if you

find this one particular chemical it means it has been irradiated. But the fact is that as the dose goes up the more products are produced in the product, but that is the same thing that occurs with cooking, for example. The higher the temperature at which you cook, or if you broil the food rather than bake the food it produces a whole new set of chemicals in it, and that is what happens with irradiation as well. It is not surprising.

The real question is: Are those residues toxic? That is the real issue, and the data, as I said before, for these high levels, is that, there has been no evidence of toxicity at these high levels, but there were certain flaws in the studies that would lead us to say, still being very cautious, that we need more work in order to be certain that those flaws are covered. So, yes, there are changes, but we don't believe, thus far there is evidence those changes produce toxic residues.

Mr. BEDELL. If there was toxicity, would that be likely to cause malignancies?

Dr. MILLER. Not necessarily. It depends on the nature of the chemical, and there are all kinds of toxicities in what occurs.

Mr. BEDELL. Are there any other questions?

If not, we thank you very much for your testimony and for your work in this area.

Dr. YOUNG. Thank you, Mr. Chairman.

Mr. BEDELL. Our next panel consists of Dr. Robert Alvarez, Environmental Policy Institute, Washington, DC; Ms. Kathleen Tucker, executive director, Health and Energy Institute, Washington, DC; Dr. Catherine J. Frompovich, president, Coalition for Alternatives in Nutrition and Healthcare, Inc., Richlandtown, PA.

Again, we would request that you hold your testimony to not more than 5 minutes.

Mr. Alvarez, we will hear from you first.

STATEMENT OF ROBERT ALVAREZ, DIRECTOR, NUCLEAR WEAPONS AND POWER PROJECT, ENVIRONMENTAL POLICY INSTITUTE

Mr. ALVAREZ. Thank you very much.

My name is Robert Alvarez, director of the nuclear project of the Environmental Policy Institute. EPI is a public interest, nonprofit organization engaged in research, publication, public education, and public advocacy as they relate to environmental issues.

The Environmental Policy Institute strongly opposes enactment of H.R. 696, a bill to encourage the commercialization of food irradiation technologies. There are several compelling reasons for this.

First, the irradiation of food involves an ultrahazardous technology which poses several types of risks to the public and workers. Food irradiation facilities, as envisioned by its proponents, will utilize very large quantities of intensely radioactive substances which, even in very small quantities, can cause death from acute radiation syndrome. One food irradiation facility will be generating as much as 10 times more low-level radioactive wastes—in curie content—than all sources combined in the United States for the year 1981.

Food irradiation facilities pose serious contamination risks to local water supplies due to the potential for leaking or ruptured capsules containing radioactive sources in cooling pools.

I would like to draw your attention to an event which occurred throughout the 1970's and 1980's at an irradiation facility called International Neutronics in Dover, NJ. During the 1970's the pool of this particular facility containing cobalt-60 leaked into the water, and by the 1980's attempts were made to decommission the pool. An estimated 5,700 liters of contaminated water was released onto the irradiator building floor. The water seeped out eventually and contaminated soil outside. Moreover, employees dumped an unknown quantity of radioactive water down the shower drains.

I would request permission that the portion of the regulatory document concerning this event be put in the record.

The other issue is that the regulations governing public exposures from irradiation facilities are much more lax than for commercial nuclear powerplants. For example, citizens living near an irradiation facility are allowed to receive 20 times more radiation exposure yearly (500 millirems) than from commercial reactors (25 millirems).

Second, irradiation facilities are poorly regulated. The Nuclear Regulatory Commission has allowed industrial radiation facilities to be located in populated areas which has led to serious public health consequences. For example, a food school kitchen serving 40,000 children was heavily contaminated by a commercial radiation plant in 1979 at levels in excess of EPA standards. A variety of accidents have occurred with radioactive sources in the commercial sector. Sometimes radioactive sources are simply lost. At one facility, Radiation Technology, in New Jersey, company employees were caught by the Nuclear Regulatory Commission placing radioactive materials in a dumpster for disposal as nonradioactive garbage.

Third, the risks of occupational exposures in food irradiation facilities are considered by the NRC staff to be the most dangerous. This is because of the potential for exposure to lethal levels of radiation. In 1977, a worker at Radiation Technology, Inc. was reported by the NRC to have received a dose of 22 rads (radiation absorbed dose) which is close to the dose which would be lethal to 50 percent of the people so exposed. It also may be the largest occupational exposure to ever occur at an NRC licensed facility. The incident was directly caused by a management decision to allow the source to be raised with inoperative interlock and safety devices, in violation of license requirements. That the NRC allowed this plant to continue in operation given such a serious breach of safety is an example of the Federal Government's weak regulation of such a dangerous industry.

Occupational risks to workers chronically exposed to low-level radiation at the DOE's Hanford facility, which processes radiocesium for food irradiation, are being found to be quite serious. Hanford workers have been shown in a series of studies to have risks of dying from radiation-induced cancer which are 10 to 20 times greater than current protection standards assume.

Fourth, irradiation intended to eliminate one food hazard may intensify another. From the environmental perspective, the cre-

ation of radiation resistant bacteria and viruses pose health risks which deserve further study before food irradiation is commercialized.

Fifth, the food irradiation industry is the sole creation of the nuclear weapons industry which is desperately seeking ways to externalize their enormous nuclear waste costs. Under a scheme offered by the Department of Energy [DOE], the DOE is proposing to lease its radiocesium, then offer to transport the sources to and from facilities. After the source has been spent, but is still quite radioactive, DOE plans to return the radioactive wastes back to the Hanford facility for disposal essentially in shallow landfill facilities.

Sixth, food irradiation is another nuclear boondoggle that will require multimillion dollar subsidies from the taxpayer for a technology with no proven history of commercial success. If left to fend for itself in the marketplace, the food irradiation industry would have been dead by the late 1950's. The major subsidies by the nuclear weapons program over the years—which for the most part was decided in secrecy—has more to do with the viability of food irradiation than its commercial need.

Finally, H.R. 696 is a bill that abrogates the rights of States to protect the health and safety of its citizens. The proposed legislation forbids State and local governments from regulating food irradiation independently and forbids them from requiring consumer labeling or other consumer protection not required under Federal law.

Mr. BEDELL. How much more time do you need?

Mr. ALVAREZ. These are my recommendations. I will be done in 1 minute.

In addition to not allowing H.R. 696 to become law, the Congress should take the following steps: require environmental impact statements for all federally subsidized efforts to commercialize food irradiation; require labeling, if the Food and Drug Administration does not; convene an independent review of the actual commercial and technological viability of food irradiation through the Office of Technology Assessment; and hold up funds for the construction of food irradiation facilities in the DOE budget until such an assessment is done.

This concludes my testimony. Thank you very much.

[The prepared statement of Mr. Alvarez appears at the conclusion of the hearing.]

Mr. BEDELL. Ms. Tucker, did you have testimony as well?

Ms. TUCKER. Yes, I do.

Mr. BEDELL. You may proceed.

STATEMENT OF KATHLEEN M. TUCKER, PRESIDENT, HEALTH AND ENERGY INSTITUTE

Ms. TUCKER. Thank you for the opportunity to testify before your subcommittee this morning regarding the hazards of food irradiation. We are appalled by Food and Drug Administration proposals to allow secret irradiation of our fresh fruits, vegetables and grains with ionizing radiation either from gamma sources like cobalt-60 or cesium-137 or by machine sources of x rays of electron beams. Our concerns are listed in great detail in the comments which the

Health and Energy Institute and the Environmental Policy Center submitted to the FDA and which we have provided to this subcommittee. We respectfully request that these comments be made part of this hearing record.

Our comments are far too extensive to summarize in a mere 5 minutes. The Health and Energy Institute opposes H.R. 696, the Federal Food Irradiation Development and Control Act of 1985, because it is economically unsound, infringes on States' rights and promotes an unsafe technology which can endanger both human health and our physical environment.

Using ionizing radiation to preserve food is like using a chain saw to cut butter. Our Federal tax dollars should not be wasted promoting such a technology, as sought by H.R. 696. We believe food irradiation brings more false promises from the nuclear industry. Once we were told that nuclear power would be too cheap to meter. Now the electrical nuclear power industry has proven exorbitantly expensive and some utilities feel it will bankrupt them.

Irradiated food will be more expensive. Extending the shelf life of chicken or fish an extra week could cost around 5 cents more per pound. Food irradiation will require greater centralization of food processing, because food irradiation facilities are capital intensive ventures. Noel F. Sommer of the University of California at Davis, a postharvest pathologist, notes that costs of a facility must also include such items as refrigeration and transportation of produce to and from facilities. Promoters sometimes pull their figures out of the air, he warns. Often these figures have been greatly underestimated.

Writing to the FDA in June 1981, Griffith Laboratories U.S.A., a food processor, pointed out that:

> According to published figures, radiation processing of spices would be approximately three times as costly as current acceptable processes . . . We do not see any favorable economic benefit, but rather the reverse, especially on the small manufacturers.

Tax dollars should not be used to subsidize industries that will make our foods more expensive and require greater centralization of the food distribution system. Tax dollars can be spent more wisely to aid farmers instead of middlemen in the American market.

H.R. 696 will change current law so that labeling of irradiated foods to the consumer will no longer be required by the Federal Food, Drug and Cosmetic Act. This is by reclassifying it from a food additive to a food process. Current law requires a straightforward statement, "Treated with ionizing radiation." Consumer acceptance studies have consistently shown that consumers are likely to avoid irradiated food if they know about it. That is why the industry is so anxious to eliminate the food labeling requirements or substitute something that will mislead the consumer.

Consumers have made it clear to the FDA that they want to know if their food is irradiated. The thousands of comments received by the FDA in response to their proposed rulemaking overwhelming opposed secrecy in labeling. Both the States of Oregon and Vermont are considering legislation to require that irradiated foods be labeled to consumers.

H.R. 696 forbids State and local governments from regulating food irradiation independently of the Federal Government and forbids them from requiring consumer labeling or other consumer protection not required under Federal law. This is an outrageous effort to shield a dangerous technology from elected officials who try to protect their constituents. Consumers should be given the opportunity to avoid irradiated food, because serious questions have been raised by reputable scientists about consuming such food.

The safety of consuming irradiated foods is open to serious doubt. Many scientists from colleges and universities across this Nation have urged the FDA to delay action on irradiated foods until more is known about the hazards. Scientific studies have already demonstrated such problems as: One, the loss of vitamins and nutritional quality in foods which are irradiated; two, the potential for genetic damage and cancer resulting from eating irradiated foods; three, increased growth of naturally occurring aflatoxins, which are potent cancer-causing agents due to the irradiation process; four, creation of new chemicals in the food, called radiolytic products by the ionizing process; and, five, increased risk of food poisoning caused by the radiation resistant botulism bacteria.

The FDA discounted the need to determine the overall effects on a diverse population of eating a variety of irradiated foods over a lifetime. The FDA declared irradiated food safe by ignoring the evidence of a variety of scientific studies. An FDA memorandum dated April 9, 1982 states that a task force reviewed 441 studies and initially accepted 266. Using certain criteria, they eliminated many studies and examined in detail 32 studies indicating adverse results of eating irradiated foods and 37 studies that appeared to support safety. Next they declared all but five studies—which supported safety—"deficient."

I have been trained as a lawyer and when you find that there were 32 for and 37 against or something in that nature one would regard that as a debate instead of a consensus on the safety of something, but what the FDA did——

Mr. BEDELL. Are you about through?

Ms. TUCKER. I would beg for additional time.

Mr. BEDELL. How much additional time, because we are going to have to be pretty strict here. How much time do you need?

Ms. TUCKER. Could I have another 4 minutes, please.

Mr. BEDELL. What are the wishes of the subcommittee?

Mr. BROWN. I would like to ask permission for her to have another 4 minutes.

Mr. BEDELL. Without objection.

Ms. TUCKER. Thank you very much.

We do not think it is appropriate to base the safety of a hazardous process on five studies, ignoring a vast literature containing evidence suggesting that irradiated foods may be hazardous to our health.

In a review of 1,223 wholesomeness studies conducted by J. Barna for the Hungarian Academy of Sciences in 1979, study results were classified as either neutral, adverse or beneficial. Each study could have several outcomes, since studies could address more than one issue. Barna found 1,414 adverse effects, 185 benefi-

cial effects and 7,191 neutral effects. Clearly, there is research evidence suggesting potential harm to humans.

Barna provided breakdowns for items considered, and I will provide some examples. For bacon, he found 86 neutral study results, 31 adverse study results and no beneficial results. For soybeans he found 60 adverse study results, no beneficial results and 26 neutral study results. For sucrose, a very common food component, he found 39 adverse study results, 38 neutral, and one beneficial. For corn oil he found 13 adverse, 5 neutral, and no beneficial results.

The studies reviewed by Barna were those considered by a so-called expert committee on wholesomeness sponsored by the International Atomic Energy Agency and others. This so-called expert committee declared irradiated food safe. The International Atomic Energy Agency is not a public health organization; its mandate is to promote nuclear technologies. We contend their declaration of wholesomeness is analogous to claims by the American Tobacco Institute that cigarette smoking has not been proven dangerous to one's health.

I would like to draw the subcommittee's attention to a couple of studies indicating adverse effects to support our overall concern.

In a study of feeding freshly irradiated wheat to malnourished children, conducted in India, children fed freshly irradiated wheat developed blood abnormalities—polyploid cells associated with cancer induction—while control children fed the same diet did not show this problem. The wheat was irradiated at the same levels as proposed now in the United States. The study was published in a scientific journal, The American Journal of Clinical Nutrition. Food irradiation promoters have suggested that the study was fraudulent, and they claimed it was repudiated by the director of the institute conducting the study. We wrote to the institute, and we have attached their response, which indicates that they stand behind their study. And also that the institute cited as claiming that the study was fraudulent—never made such a claim. In fact, similar problems with freshly irradiated wheat have been demonstrated in the blood of both monkeys and mice.

Another study looked at drosophila melanogaster—fruit flies—for genetic damage when fed irradiated chicken. That study found that fruit flies fed gamma irradiated chicken have seven times fewer offspring than those fed thermally processed chicken. Donald W. Thayer of the Department of Agriculture considered this finding alarming, and worthy of further investigation.

We believe that the scientific literature thus far creates controversy over the safety of feeding irradiated foods to our children. We, therefore, recommend the following: Commercialization of food irradiation should be halted; an environmental impact statement should be prepared for the food irradiation process before more funds are committed or spent for development in this field; the many unanswered questions about the safety of eating irradiated foods should be addressed by agencies that do not promote nuclear technologies, such as the Department of Energy; H.R. 696 should not be passed into law; and any food or food ingredient that has been irradiated with ionizing radiation should be clearly labeled to the consumer as required by current regulations.

We do not want to see a misleading Sunshine symbol as has been suggested by some members of the industry.

I would like to present several hundred signatures on petitions opposing food irradiation, along with documents attached to my testimony describing cesium-137 and cobalt-60, the radioactive substances that the industry wants to use, the DOE projects that have been funded in secret hearings and some of the scientific study information which I have cited.

Thank you.

[The prepared statement of Ms. Tucker appears at the conclusion of the hearing.]

Mr. BEDELL. Dr. Frompovich.

STATEMENT OF CATHERINE J. FROMPOVICH, PRESIDENT, COALITION FOR ALTERNATIVES IN NUTRITION AND HEALTHCARE, INC.

Ms. FROMPOVICH. Thank you for the opportunity to present comments in opposition to food irradiation.

The issue of primary concern to us is that of safety which involves the various aspects, phases, and techniques used in the food irradiation process together with contradicting or questionable information on research and testing.

In many instances a very definite toxic effect was observed in some phase of the investigation, clearly associated with the irradiation, and this was so stated. However, when the final evaluation of the study was summarized, this observation was somehow lost and the conclusions stated that there were no toxic effects that could be associated with irradiation.

A toxic effect has been observed in some phase of the experiment and was noted as being clearly associated with irradiation. Somehow through several reports and interpretations the observation became less and less significant until it disappeared. Ultimately, the writer concluded that the irradiated food had been more beneficial for the animals than the control diet.

The most serious question in my mind is: Will there be genetic mutations as a result of food irradiation? In a statement submitted by Radiation Technology, Inc., a petitioner to USDA/FDA for food irradiation licensing, the following information appears: "Mutations are an inevitable consequence of irradiating foods, yet the creation of new organisms and/or organisms with increased pathogenicity is not a probable event for the following three reasons," (a), (b) and (c) and (c) says, "Changes in DNA will induce DNA repair mechanisms so many mutations will only be temporary (Ingram and Farkas 1977)."

Still another question: How can one say DNA mutations will only be temporary? Who is to say who will be subject to the mutations? What right does private industry or anyone else have to reprogram DNA repair mechanisms?

The report from which I recite this statement is known as "Finding of No Significant Impact" for Food Additive Petition 4M3789, submitted by Radiation Technology, Inc. which concerns the use of gamma irradiation to control trichinae and other helminths in pork. Send to DMB Docket No. 84F-0230. Approved date: January

28, 1985. May I ask that this information be made part of the public hearings on record.

Mr. BEDELL. Without objection.

Ms. FROMPOVICH. Still another question: Why did the FDA approve pork irradiation just 3 days before the new EPA guidelines would have required an environmental impact report?

Regarding the studies to support safety of food irradiation processing, my question is why only "5 studies appeared to support safety, and all the remaining 64 were determined to be deficient"? Originally, 441 summarized studies were presented; of that 266 were accepted or accepted with reservation, 147 were rejected and 28 were not categorized and only 5 appeared to support safety. This poses another question: How can food irradiation be deemed safe based upon such a minute number of accepted studies? This information appears in a Department of Health and Human Services Memorandum from Food Additives Evaluation Branch, HFF-156, dated April 9, 1982 for the subject: "Final Report of the Task Group for the Review of Toxicology Data on Irradiated Foods." May I ask that this information be made part of the public hearings on record.

Mr. BEDELL. Without objection.

Ms. FROMPOVICH. Still another question: How can a petitioner for the irradiation process claim that labeling not be required? In a letter dated July 30, 1985 from Radiation Technology, Inc. to USDA-FSIS, its president, Martin Welt, states:

> Although the FDA is required by current regulation to consider food irradiation an additive, I believe that the FSIS can do away with a carrythrough labeling requirement on the grounds that the additive would only be considered incidental to the process and not of any substantive value.

Pasteurization is required by law to be on a label and so should irradiation along with the number of rads used to irradiate the foods or any food component.

May I ask that this be made part of the record.

Mr. BEDELL. Without objection.

Ms. FROMPOVICH. And my final question: How come there are no food irradiation guidelines? In my letter of August 27, 1985, to Dr. Engel at USDA, I asked if there were guidelines for irradiation doses and rads similar to the manual on chemicals known as "Compound Evaluation and Analytical Capability Annual Residue Plan." Dr. Engel asked Dr. George Pauli of Division of Food and Color Additives, HFF-330, Center for Safety and Applied Nutrition, to answer my question which he did in his letter dated October 10, 1985. Dr. Pauli said: "We have no such guidelines." Why?

Mr. BEDELL. Excuse me, Dr. Frompovich. What is your situation with regard to time?

Ms. FROMPOVICH. About a half a minute. May I have it, please?

Mr. BEDELL. You may proceed, of course.

Ms. FROMPOVICH. Thank you.

If there are no food irradiation guidelines, how can the process possibly be approved?

In summation, I would like to request that much more impeccable research be done at various levels before our government considers this process. In addition, I respectfully request the FDA to

withdraw its present approvals on the foods already approved for the food irradiation process.

[The prepared statement of Ms. Frompovich appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much.

Mr. Roberts.

Mr. ROBERTS. Yes, Mr. Chairman.

I said in my earlier statement at the beginning of these hearings that judging from the witness list I thought we would hear from all sides of the issue, and I looked forward to that. We certainly have had that with this panel. I want to thank you for your comments and for your statements. That is what this hearing is all about. You have asked some good questions, and I think as we go through these hearings, why, we will try to answer them as best we can.

Ms. FROMPOVICH. Excuse me. May I have some input to you, sir?

Mr. ROBERTS. Yes, ma'am.

Ms. FROMPOVICH. Could we possibly be considered as resource individuals on this issue?

Mr. ROBERTS. I beg your pardon?

Ms. FROMPOVICH. May we be considered as resource individuals on this issue?

Mr. ROBERTS. I think everybody that is going to testify will be resource people in terms of the testimony that they provide.

Ms. FROMPOVICH. Thank you.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. Alvarez, you make a number of allegations concerning the relationship between food irradiation and the nuclear industry. Do you have the same attitude toward medical irradiation?

Mr. ALVAREZ. No, sir. In fact, if I may with permission, this is my wife, Kitty Tucker. Kitty had Hodgkin's disease in 1963 and was treated with irradiation, and I believe very strongly it saved her life; but I think there are limits to this, and there are beneficial uses of irradiation. There is no question about that, but at the same time there are uses of irradiation which in my view pose unacceptable risks to society, and in my opinion food irradiation is one of those.

Mr. MORRISON. Then your questions about facilities and the relationship with the nuclear industry, you say those do not apply to medical treatments or sterilization of the various things used in hospitals?

Mr. ALVAREZ. No, I make no such claims. A great deal of the isotopes for the use of medicine came from the Federal Nuclear Program.

Mr. MORRISON. But you do not want it applied to food, even though it is the same process.

Mr. ALVAREZ. Well, I think that it is pretty clear that the commercial use of radioisotopes for medicine have been shown to be commercially viable without a significant heavy Federal subsidy over the years. However, I would say that if food irradiation were to fend for itself around the same time that the radioisotope industry had to fend for itself, which was the late 1950's, food irradiation would probably be a footnote in history books.

May I make another comment about this. You see, food irradiation to me appears to be more of a product of glacial bureaucratic drift than commercial viability. The primary source of funds for food irradiation are not coming from the U.S. Department of Agriculture but they are coming right out of the nuclear weapons budget. Now that raises a question: Is the nuclear weapons program an agency involved in food safety?

Mr. MORRISON. Are you aware that the separation of cesium that you included in your comments is finished? There will be no more; that is, it is much too expensive and they are aware of that now.

Mr. ALVAREZ. Yes, I am aware of that, and I am also aware that there are at least some plans that are being entertained at the Savannah River Plant to separate cesium so the possibilities that more irradiation in the form of cesium cannot be ruled out is my understanding.

Mr. MORRISON. My understanding is that the separation that was done in Hanford in my district was because the material—it reduced the threat of the radioactive defense wastes that were in storage in tanks that were designed for 25 years and lo and behold after 30 years some of them started to leak so that that separation was made, and it was an expensive separation of materials. There were about 77 million curies there, and it has been oversubscribed by twice. Most of that will be used for medical purposes. In fact, one of the reasons for H.R. 696 was to get food irradiation added to the list of use, priority use for any radioisotopes the government may happen to have title to. I guess the point is this. There will be no tie as far as future food irradiation is concerned back with the nuclear industry in any way, shape or form.

Cobalt is produced commercially. It does not have a tie except in Canada to the use of irradiation sources, and I anticipate, as I see it, that these source materials will be machine generated and have absolutely no relationship to the nuclear industry. Does that render moot then many of the arguments that you make in your paper?

Mr. ALVAREZ. With all due respect, Congressman, I say that they do not because if you just look and see what is happening, the Department of Energy is spending the lion's share of the money for the commercialization of this process, and the lion's share of that money is going for the utilization of radiocesium sources.

In Dublin, CA there is at least plans to construct a major cesium irradiator. There is a mobile irradiator that is planned to be hauled around the farmland of the Northwest. I respectfully disagree, sir.

Mr. MORRISON. Those are demonstration facilities. The point that I am making is that cesium, which you seem to count on, they are not going to separate. It is expensive to separate, and at half the cost of cobalt they cannot afford to do it.

Mr. ALVAREZ. I understand, sir, but there is, I believe, at least depending on what you read somewhere between 80 and 90 million curies of radiocesium.

Mr. MORRISON. Yes, and there are 144 million curie requests for that.

Mr. ALVAREZ. I understand. Also by 1985—10 years ago there were requests for 264 nuclear powerplants, but they just did not happen, so I think we have to look at reality.

Just to summarize, I think that this radiocesium that has been separated at Hanford will have to be disposed of as radioactive wastes unless it is commercialized, and thus millions of dollars would have been poured down the drain.

Mr. MORRISON. Well, it has a very great beneficial use, Mr. Alvarez. Some of it goes toward food processing. I think that would be no different for society as long as it is safe and the Food and Drug Administration is handling it than it would be for the handling for the sake of medical, which you seem to support.

Mr. ALVAREZ. I respect your views, sir.

Mr. MORRISON. I thank you, sir.

Mr. Chairman, I wish I had more time.

Mr. BEDELL. Mr. Brown.

Mr. BROWN. No questions.

Mr. BEDELL. Mr. Panetta.

Mr. PANETTA. Mr. Chairman, first of all, I would like to ask unanimous consent that a statement that I prepared be inserted in the record.

Mr. BEDELL. Without objection.

[The prepared statement of Mr. Panetta follows:]

STATEMENT OF REPRESENTATIVE LEON E. PANETTA
TO AGRICULTURE SUBCOMMITTEE ON DEPT. OPERATIONS, RESEARCH, AND FOREIGN OPERATIONS

NOVEMBER 18, 1985

Mr. Chairman, Subcommittee Members, thank you for scheduling this hearing today to consider issues concerning the use of food irradiation and to review H.R. 696, a bill designed to provide Federal coordination for the continued research, development, and commercialization of food irradiation.

I believe it is extremely important that we hold forums like this to fully address public concerns on this issue. As you know, recent actions at the federal level have prompted a great deal of debate concerning the safety and wholesomeness of food irradiation. As I have stated before, since this technology holds the potential to replace highly toxic and carcinogenic post-harvest pesticides, I believe that it deserves further research. However, it is very important that evidence on all sides of the irradiation issue are brought to light and fully examined to insure that this technology presents no health hazards. It is also important that if the technology is found to be safe, that consumers be made aware of the fact that food is irradiated so that they can make their own decisions. Labeling is an important part of any proposal on this issue.

There is clearly a great deal of confusion regarding the impact and intent of recent federal actions pertaining to food irradiation. The public should be aware that such actions include both the proposed regulatory changes by the FDA that were released for public comment in 1984, and legislation which has been introduced in Congress to provide Federal coordination for the research, development, and commercialization of food irradiation.

In this regard, there is additional concern about the impact that H.R. 696 would have on food irradiation labeling requirements. In order to clarify this issue, I wrote to the Food and Drug Administration (FDA). In a letter of response, the Agency states that "it is not aware of any provisions in H.R. 696 that would affect federal food irradiation labeling requirements". At this time, I would like to submit a copy of the Agency's letter for the record. It is my understanding that current Federal regulations require that irradiated foods must be labeled at both the retail and wholesale level. However, to date, since very few foods have been irradiated on a commercial basis, consumers rarely see labels at the retail level which indicate that the food has been irradiated. I also want to point out that in 1984 the FDA did propose changes in its regulations concerning food irradiation which would affect labeling requirements. To date, no action has been taken on the proposed changes and the Agency will be taking into consideration approximately 5,000 comments that it received on this matter before issuing a final rule.

I would like to take a moment to provide some background on recent

federal actions in this area. First, in 1984, the federal Food and Drug Administration (FDA) proposed rules which would permit the use of low-dose ionizing radiation (at 100 kilorads) to control insect infestation and delay the ripening of fresh fruits and vegetables. One major concern with this proposed rule has been the issue of consumer labeling. Current regulations require irradiated foods to be clearly labeled. The proposed rule would only require labeling at the wholesale, but not the retail level. As I have stated before, I firmly believe that all irradiated foods must be clearly labeled at both levels. FDA is now in the process of reviewing the comments received and deciding whether amendments to the proposed regulations are warranted. Final regulations will be published once that process is complete.

Second, Rep. Sid Morrison has introduced H.R. 696, which would establish a Joint Operation Commission to coordinate research efforts and promote activities that would facilitate the exchange of information and encourage open public discussion of this technology. The bill would also redefine irradiation from a food additive to a food process status. As stated in FDA's letter, this bill would not affect federal food irradiation labeling requirements.

Currently, limited uses of food irradiation have been approved. They include irradiation of spices to reduce the count of microorganisms, irradiation of wheat and wheat flour to control insects, irradiation of potatoes to inhibit sprouting, and the most recent ruling that allows irradiation of pork to control trichinosis. However, at this time, commercial use of food irradiation is not extensively used on any of these food products in the U.S.

As a result of the ethylene dibromide (EDB) suspension and the recent medfly crises in California and Florida, interest has been renewed in the use of irradiation as a viable alternative for highly toxic post-harvest pesticides. As you know, EDB was banned for agricultural use in 1984 by the Environmental Protection Agency because it was found to be a carcinogen. EDB had been popularly used as a post-harvest fumigant on fresh fruit to prevent the spread of tropical fruit flies. Unlike EDB and other toxic pesticides, irradiation will not leave a toxic residue on the food.

I have carefully monitored the issue of food irradiation since 1981, when FDA first announced its intention to publish new regulations. Because there now is evidence that this technology holds the potential to replace highly toxic pesticides, insecticides, and other chemical preservatives, I believe that this technology deserves further research and consideration. While evidence to date indicates that food irradiation can be safely used at low doses and for uses specified in FDA's proposed rule, I believe that further research is warranted before food irradiation can be widely expanded on a commercial basis.

Again, I want to thank the Chairman and the Subcommittee for providing the opportunity to discuss these important issues in this public forum.

(Attachments follow:)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

OCT 31 1985

The Honorable Leon E. Panetta
House of Representatives
Washington, D.C. 20515

Dear Mr. Panetta:

This is in response to your letter of September 12 to Commissioner Young concerning the potential impact of H.R. 696, the "Federal Food Irradiation Development and Control Act of 1985," on food irradiation labeling requirements. This letter also confirms information exchanged on October 22 between Ms. Liz Turner of your staff and Dr. George Pauli of our Center for Food Safety and Applied Nutrition. You asked two questions. Our responses are as follows:

Question #1: Outline current food irradiation labeling requirements and implementation measures. In addition, please advise me as to whether these food irradiation labeling requirements are strictly adhered to.

Answer: The current labeling requirements for foods treated with ionizing radiation are found in Title 21, Code of Federal Regulations, sections 179.22 and 179.24 (copy enclosed). All labels and labeling must bear the statement "Treated with ionizing radiation" on retail packages and "Treated with ionizing radiation-do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipment. In any of these statements, the word "ionizing" may be replaced by "gamma" or "electron" as appropriate.

FDA has interpreted these requirements to apply only to foods directly irradiated, not to ingredients that may have been previously irradiated, such as spices, but are then added to a food which has not been irradiated.

Last year FDA proposed additional regulations for using ionizing radiation for treating foods. 49 Federal Register, 5714; February 14, 1984. The proposal also invited public comment on labeling issues. The Agency is currently reviewing approximately 5,000 comments that were received in the rulemaking proceeding.

The amount of food irradiated appears to be small, and consists primarily of spices and seasonings used as ingredients in other foods. We are unaware of any commercial irradiation of food for retail sale. Therefore, the labeling issue has not yet become significant from a practical regulatory standpoint. We have not had the occasion to take regulatory action involving irradiated food for labeling reasons.

Question #2: Evaluate and identify how H.R. 696 may affect food irradiation labeling requirements.

Answer: We are not aware of any provisions in H.R. 696 that would affect federal food irradiation labeling requirements. However, section 4 of H.R. 696 contains a specific preemption provision that would prevent a state from imposing additional or different labeling requirements on irradiated foods.

The Agency's labeling authority is generally set forth at sections 403 and 409 of the Federal Food, Drug, and Cosmetic Act (21 USC §§343 and 348). H.R. 696 would not change these sections relative to food irradiation labeling requirements except to add the words "or process" after the words "the additive" in section 409(c)(3)(B). Thus we believe this bill would not substantively change federal food irradiation labeling requirements.

I hope this information is helpful to you. If we can be of further assistance, please let us know.

Sincerely yours,

Hugh C. Cannon
Associate Commissioner
for Legislative Affairs

Enclosure
Title 21 CFR, sections 179.22 and 179.24

List of substances	Limitations
Palmitic acid amide	
Petrolatum	Conforming to the identity prescribed in § 178.3700.
Polyethylene glycol (molecular weight 300 or greater)	Mono- and diethylene glycol content not to exceed a total of 0.2 pct.
Stannous stearate	
Stearic acid amide	
Stearyl stearate	
Tetralis[methylene (3,5-di-tert-butyl-4-hydroxyhydrocinnamate)] methane (CAS Registry No. 6683-19-8)	For use at a level not to exceed 0.5 percent by weight of the finished surface lubricant formulation.
Triethylene glycol	Diethylene glycol content not to exceed 0.1 pct.
Wax, petroleum	Complying with § 178.3710.

(c) The substances identified in paragraph (a)(2) of this section may be used in surface lubricants used to facilitate the drawing, stamping, and forming of metallic articles from rolled foil and sheet stock provided that total residual lubricant remaining on the metallic article in the form in which it contacts food does not exceed 0.015 milligram per square inch of food-contact surface.

(d) Subject to any prescribed limitations, the quantity of surface lubricant used in the manufacture of metallic articles shall not exceed the least amount reasonably required to accomplish the intended technical effect and shall not be intended to nor, in fact, accomplish any technical effect in the food itself.

(e) The use of the surface lubricants in the manufacture of any article that is the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter must comply with any specifications prescribed by such regulation for the finished form of the article.

(f) Any substance that is listed in this section and the subject of a regulation in Parts 174, 175, 176, 177, 178 and § 179.45 of this chapter shall comply with any applicable specifications prescribed by such regulation.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348); secs. 409, 701(e), 706, 70 Stat. 919 as amended, 72 Stat. 1784-1788 as amended, 74 Stat. 399-407 as amended (21 U.S.C. 348, 371(e), 376))

[42 FR 14609, Mar. 15, 1977, as amended at 48 FR 238, Jan. 4, 1983; 49 FR 10113, Mar. 19, 1984; 49 FR 29579, July 23, 1984]

§ 178.3930 Terpene resins.

The terpene resins identified in paragraph (a) of this section may be safely used as components of polypropylene film intended for use in contact with food, and the terpene resins identified in paragraph (b) of this section may be safely used as components of polyolefin film intended for use in contact with food;

(a) Terpene resins consisting of the hydrogenated polymers of terpene hydrocarbons obtainable from sulfate turpentine and meeting the following specifications: Drop-softening point of 118°–138° C; iodine value less than 20.

(b) Terpene resins consisting of polymers of beta-pinene and meeting the following specifications: Acid value less than 1; saponification number less than 1; color less than 4 on the Gardner scale as measured in 50 percent mineral spirits solution.

§ 178.3940 Tetraethylene glycol di-(2-ethylhexoate).

Tetraethylene glycol di-(2-ethylhexoate) containing not more than 22 parts per million ethylene and/or diethylene glycols may be used at a level not to exceed 0.7 percent by weight of twine as a finish on twine to be used for tying meat provided the twine fibers are produced from nylon resins complying with § 177.1500 of this chapter.

§ 178.3950 Tetrahydrofuran.

Tetrahydrofuran may be safely used in the fabrication of articles intended for packaging, transporting, or storing foods, subject to the provisions of this section.

(a) It is used as a solvent in the casting of film from a solution of polymeric resins of vinyl chloride, vinyl acetate, or vinylidene chloride that have been polymerized singly or copolymerized with one another in any combina-

tion, or it may be used as a solvent in the casting of film prepared from vinyl chloride copolymers complying with § 177.1980 of this chapter.

(b) The residual amount of tetrahydrofuran in the film does not exceed 1.5 percent by weight of film.

§ 178.3970 Ultramarine blue.

Ultramarine blue may be safely used as a component of articles intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food in accordance with the following prescribed conditions:

(a) It is used as a colorant in the manufacture of the following articles:

(1) Flexible, semirigid, and rigid plastic materials.

(2) Textiles and textile fibers as provided in § 177.2800 of this chapter.

(b) The quantity used shall not exceed the amount reasonably required to accomplish the intended effect.

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING AND HANDLING OF FOOD

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

Sec.

179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

179.22 Gamma radiation for the treatment of food.

179.24 Low-dose electron beam radiation for the treatment of food.

179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

179.39 Ultraviolet radiation for the processing and treatment of food.

Subpart C—Packaging Materials for Irradiated Foods

179.45 Packaging materials for use during the irradiation of prepackaged foods.

AUTHORITY: Secs. 409, 701, 52 Stat. 1055-1056 as amended, 72 Stat. 1785-1786 as amended (21 U.S.C. 348, 371), unless otherwise noted.

SOURCE: 42 FR 14635, Mar. 15, 1977, unless otherwise noted.

Subpart A—[Reserved]

Subpart B—Radiation and Radiation Sources

§ 179.21 Sources of radiation used for inspection of food, for inspection of packaged food, and for controlling food processing.

Sources of radiation for the purposes of inspection of foods, for inspection of packaged food, and for controlling food processing may be safely used under the following conditions:

(a) The radiation source is one of the following:

(1) X-ray tubes producing X-radiation from operation of the tube source at energy levels of 300 kilovolt peak or lower.

(2) Sealed units producing radiations at energy levels of not more than 2.2 million electron volts from one of the following isotopes: Americium-241, cesium-137, cobalt-60, iodine-125, krypton-85, radium-226, and strontium-90.

(3) Sealed units producing neutron radiation from the isotope Californium-252 (CAS Reg. No. 13981-17-4) to measure moisture in food.

(b) To assure safe use of these radiation sources:

(1) The label of the sources shall bear, in addition to the other information required by the Act:

(i) Appropriate and accurate information identifying the source of radiation.

(ii) The maximum energy of radiation emitted by X-ray tube sources.

(2) The label or accompanying labeling shall bear:

(i) Adequate directions for installation and use.

(ii) A statement that no food shall be exposed to radiation sources listed in paragraph (a) (1) and (2) of this section so as to receive an absorbed dose in excess of 1,000 rads.

(iii) A statement that no food shall be exposed to a radiation source listed in paragraph (a)(3) of this section so as to receive an absorbed doese in excess of 200 millirads.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 46022, Oct. 11, 1983]

§ 179.22 Gamma radiation for the treatment of food.

Gamma radiation for the treatment of certain foods may be safely used under the following conditions:

(a) The radiation source consists of sealed units containing the isotope cobalt-60 or cesium-137.

(b) The gamma radiation is used or intended for use in a single treatment as follows:

Food for irradiation	Limitations	Use
Garlic powder; Onion powder, Spices, dried: allspice; anise; basil; bay leaves; caraway seed; cardamon; celery seed; chervil; cinnamon; cloves; coriander; cumin seed; dill seed; fennel seed; fenugreek; ginger; horseradish; mace; marjoram; mustard seed; mustard flour; nutmeg, oregano; paprika; parsley; pepper, black; pepper, white; pepper, red; rosemary; saffron; sage; savory; star aniseed; tarragon, thyme; turmeric.	Absorbed dose: Not to exceed 10 kiloGray (kGy) (1 megarad (Mrad))	Control of insects and/or microorganisms.
Wheat	Absorbed dose: 20,000 to 50,000 rd	Control of insect infestation.
Wheat flour from unirradiated wheat.	do	Do.
White potatoes	Absorbed dose: 5,000 to 15,000 rd	Inhibit sprout development.

(c) To assure safe use, the label and labeling of the food shall bear, in addition to the other information required by the act, the following statements:

(1) "Treated with ionizing radiation" or "Treated with gamma radiation" on retail packages.

(2) "Treated with ionizing radiation—do not irradiate again" or "Treated with gamma radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments.

(Secs. 201(s), 409, 72 Stat. 1784-1788 as amended (21 U.S.C. 321(s), 348))

[42 FR 14635, Mar. 15, 1977, as amended at 48 FR 30614, July 5, 1983; 49 FR 24989, June 19, 1984]

§ 179.24 Low-dose electron beam radiation for the treatment of food.

Electron beam radiation for the treatment of food may be safely used under the following conditions:

(a) The radiation source consists of an electron accelerator producing a beam of electrons at energy levels not to exceed 5 million electron volts.

(b) The electron beam radiation is used or intended for use in a single treatment as follows:

Food for irradiation	Limitation	Use
Wheat	Absorbed dose: 20,000 to 50,000 rads. Maximum thickness of food under irradiation: 0.8 cm/Mev of electron energy under single beam irradiation or 1.4 cm/Mev of electron energy with crossfiring beams. Maximum flow: 10 tons per hour per kilowatt under single beam irradiation, or 14 tons per hour per kilowatt with crossfiring beams.	Control of insect infestation.
Wheat flour from unirradiated wheat	do	Do.

(c) In the case of electron beam radiation used for treatment of food, a permanent record of the radiation intensity and power used in the processing shall be made with recorders coupled to the electron accelerator, and

the records shall be retained for Food and Drug Administration inspection for a period of 1 year. Such records shall provide information identifying completely the food that has been subjected to the radiation recorded thereon.

(d) To assure safe use, the label and labeling of the food shall bear, in addition to the other information required by the act, the following statements:

(1) "Treated with ionizing radiation" or "Treated with electron radiation" on retail packages.

(2) "Treated with ionizing radiation—do not irradiate again" or "Treated with electron radiation—do not irradiate again" on wholesale packages and on invoices or bills of lading of bulk shipments.

§ 179.30 Radiofrequency radiation for the heating of food, including microwave frequencies.

Radiofrequency radiation, including microwave frequencies, may be safely used for heating food under the following conditions:

(a) The radiation source consists of electronic equipment producing radio waves with specific frequencies for this purpose authorized by the Federal Communications Commission.

(b) The radiation is used or intended for use in the production of heat in food wherever heat is necessary and effective in the treatment or processing of food.

§ 179.39 Ultraviolet radiation for the processing and treatment of food.

Ultraviolet radiation for the processing and treatment of food may be safely used under the following conditions:

(a) The radiation sources consist of ultraviolet emission tubes designed to emit wavelengths within the range of 2200–3000 Angstrom units with 90 percent of the emission being the wavelength 2537 Angstrom units.

(b) The ultraviolet radiation is used or intended for use as follows:

Irradiated food	Limitations	Use
Food and food products	Irradiated with 2,200 to 3,000 A. emissions, without ozone production; high fat-content food irradiated in vacuum or in an inert atmosphere; intensity of radiation, 1 W (of 2,537 A. radiation) per 5 to 10 ft.²	Surface microorganism control.
Potable water	Irradiated with 2,200 to 3,000 A. emissions, without ozone production; coefficient of absorption, 0.19 per cm or less; flow rate, 100 gal/h per watt of 2,537 A. radiation; water depth, 1 cm or less; lamp-operating temperature, 36° to 46° C.	Sterilization of water used in food production.

Subpart C—Packaging Materials for Irradiated Foods

§ 179.45 Packaging materials for use during the irradiation of prepackaged foods.

The packaging materials identified in this section may be safely subjected to irradiation incidental to the radiation treatment and processing of prepackaged foods, subject to the provisions of this section and to the requirement that no induced radioactivity is detectable in the packaging material itself:

(a) The radiation of the food itself shall comply with regulations in this part.

(b) The following packaging materials may be subjected to a dose of radiation, not to exceed 1 megarad, unless otherwise indicated, incidental to the use of gamma radiation in the radiation treatment of prepackaged foods:

(1) Nitrocellulose-coated or vinylidene chloride copolymer-coated cellophane complying with § 177.1200 of this chapter.

(2) Glassine paper complying with § 176.170 of this chapter.

(3) Wax-coated paperboard complying with § 176.170 of this chapter.

(4) Polyolefin film prepared from one or more of the basic olefin polymers complying with § 177.1520 of this chapter. The finished film may contain:

Mr. PANETTA. Also a letter sent to me from Ida Honorof to be included in the record as well.

Mr. BEDELL. Without objection.

[The letter appears at the conclusion of the hearing.]

Mr. PANETTA. Let me ask of all members of the panel, obviously the issue here is one that involves some degree of dispute and yet some feeling that if it is found to be safe, that it can be useful.

Do you have any objection to additional research into the use of irradiation?

Ms. TUCKER. I feel that there needs to be additional research into the safety of irradiated foods before there is any movement forward to commercialize it in the United States. If we move forward with the current FDA proposals, what we are saying is let's make our children and our grandchildren the guinea pigs. We are facing a rising cancer rate, a rising cancer death rate, despite spending billions of dollars trying to find cures for cancer. What we have discovered through our quick review of the literature is that every food irradiated has different radiolytic products formed in it. Now, perhaps some of these foods are safe to eat. Perhaps some of the products formed are not dangerous and perhaps others are dangerous, but in an effort to push forward a new industry that is not about to make it on its own, the Federal Government is proposing to subsidize demonstration projects through the Department of Energy. We feel that studies that have suggested adverse effects should be replicated. We feel that a lot of unanswered questions should be answered before there should be any movement forward. We do not think the research should be done on the American consumer. I think it ought to be done in the laboratory.

The study done in Indiana on real live children was done because the researchers believed the earlier research. The earlier research had only looked at stored wheat. There is nothing in the FDA proposal to require that food be stored long enough for whatever it was that caused the polyploids in these children's blood to disappear.

The replication studies indicated that they found the same kinds of problems in laboratory animals.

Mr. PANETTA. Ms. Tucker, to the extent that the legislation before us provides for unifying the research effort and trying to direct research at this issue, why would you oppose it on that basis?

Ms. TUCKER. My reading of this legislation is that they will set up a new agency to promote food irradiation just as the Atomic Energy Commission promoted new technology.

Mr. PANETTA. Would you say that about any bill that sought to do research in this area?

Ms. TUCKER. No. I think that bills looking into the safety should rightfully belong some place like Health and Human Services or the Department of Agriculture.

Mr. ALVAREZ. Sir, may I interject a comment. This bill is not a research bill. This bill is a commercialization bill and that research is designed for the goal of commercialization. It is like the Synfuels Corporation. You can say Synfuels is for R&D and for research, but where is that money truly going? It is going for the commercial demonstration. This bill makes it a policy of the Federal Govern-

ment to promote it by spending money to build plants. That is the bottom line of this bill.

Mr. PANETTA. But the Federal Government does that with a number of areas. We do that with alternatives, with energy, in the health area, in a number of areas. We are constantly involved in trying to determine whether a new technology can be workable. So what is the problem with that?

Mr. ALVAREZ. Well, there is a difference between research and development and commercialization.

Mr. PANETTA. But that is just a matter of your interpretation, isn't it?

Mr. ALVAREZ. Indeed, and in terms of research may I just make the following comments. One of the basic claims about the safety of food irradiation is that astronauts eat it. OK. Well, as you may know, the American Medical Association for many years had declared the use of irradiation of the fetus during pregnancy as safe because doctors were doing it, and they did not find anything; and in 1959 a British physican, Dr. Alice Stewart, reported that there was more than a 50 percent increased risk of dying from childhood cancer as a result of these exposures. This was occuring at the time when 26 percent of all pregnant mothers were receiving fetal x rays in the United States.

On the safety of food irradiation I would say it is comparable to the knowledge that we had about fetal x rays in the 1950's, which is nil.

Mr. PANETTA. But wait 1 minute.

You are essentially making my point.

Mr. ALVAREZ. Excuse me, sir.

Mr. PANETTA. It is my question.

Mr. ALVAREZ. I understand.

Mr. PANETTA. You are essentially making my point. The question is if there is a need for additional research into this issue, then why shouldn't we proceed with additional research? I mean the position, I take it, the panel takes is because there is a need for additional research you should not do any research.

Mr. ALVAREZ. No, sir. My position is much different than that, if you had read my statement.

My position is that our opposition to food irradiation is primarily because of the implications of this technology. This is an ultrahazardous technology that is poorly regulated, that the implications of which is that there will be a quantum jump in the amounts of intensely radioactive materials circulating in society and through communities. That in and of itself from our point of view is sufficient enough for us to oppose this technology.

However, since you did ask about food safety, I wish to draw your attention that there is a need for more research mainly because the credibility of food safety research in this country——

Mr. PANETTA. Would you support legislation to do that?

Mr. ALVAREZ. I would support legislation that would not bar the rights of States to regulate this industry. I would support legislation——

Mr. PANETTA. Answer my question. Would you support additional legislation to provide for research in food irradiation?

Mr. ALVAREZ. I would support additional legislation except I would not do it in the context of H.R. 696 and only for the purpose of determining its safety.

Mr. PANETTA. I would be interested in your comments along those lines.

Mr. ALVAREZ. Very good.

Mr. PANETTA. Thank you, Mr. Chairman.

Mr. BEDELL. Thank you.

Mr. Alvarez, you talked a little bit about the radioactive waste problem. Is this a different situation than what is used in medicine in regard to the waste that is generated?

Mr. ALVAREZ. Yes.

Mr. BEDELL. I, for one, am not sure of the difference.

Mr. ALVAREZ. You are talking about vastly larger quantities. Radioisotopes in medicine usually involve maybe a few hundred curies at a time that are in use in any given facility for the purpose of radiotherapy or diagnostic purposes.

We are talking about a facility that is going to house as much as 10 million curies of an intensive radioactive substance.

Now, in 1981, the U.S. Nuclear Regulatory Commission estimated that all sources combined including the medical industry, research industry, the Government and commercial sector, generated about 94–95 million curies of low-level radioactive waste.

Now, a food and radiation facility using a 10 million curie source, because of the fact that this radio cesium has a half life of 30 years, a certain amount of it will decay and will have to be replaced with another fresh source, and therefore you are going to have to be taking stuff out which is low level waste and putting new stuff in in order to maintain a uniform energy field.

Every 5 years they would have to replace approximately one-seventh of that source. If you do some calculations based on decay and what is left there, this means that this plant in 5 years will generate about 1.5 million curies of low-level radioactive waste that has to go somewhere.

That is substantially larger than 90-plus million curies generated from all sources combined in the United States for the year 1981.

Mr. MORRISON. Mr. Chairman, will you yield just for a moment?

We agree, Mr. Alvarez, that the radioisotopes we are talking about do not generate waste. They become wastes themselves.

Mr. ALVAREZ. That is correct.

Mr. MORRISON. So it is already out there. It is going to become waste no matter where it is so we might as well make some beneficial use of it.

It does not generate radioactivity. It cannot impart radioactivities to the structure in which it exists, and so what you are talking about is going to happen anyway.

Mr. ALVAREZ. I am not sure.

Ms. TUCKER. A big difference is if you have a very dangerous radioisotope and you have it contained in one spot, the likelihood it is going to be released into the environment and kill people, and damage the environment, is going to be much less than if you divide it up into little pieces and ship it all around the country.

Consequently, we feel it would be much more dangerous to be shipping cesium throughout the farmland in this country and

where an accident might occur and never be detected sent to facilities who may go bankrupt and leave the tridium plants in the Southwest United States.

We feel that your cesium redistribution plans through this food irradiation program will not be very beneficial to the rest of the States.

Mr. MORRISON. But you don't feel that way about the fact it is now spread all across the United States in commercial radium facilities.

Ms. TUCKER. Most facilities use cobalt 60 rather than cesium 137. At least that is what I have been informed.

Mr. MORRISON. I can assure you that the medical use and research use for cesium will far exceed the food irradiation use but, Mr. Chairman, the reason I asked for time at this point was the fact the materials that Mr. Alvarez is talking about are going to be wastes anyway and this bill includes a provision that says the Department of Energy can lease that material and then it brings it back.

So we retain the authority to make sure that the safety of these products are guaranteed as far as the public is concerned.

We are not generating more nuclear wastes. It may be generated in different places, but if in fact there can be a beneficial use for society, then obviously that problem is worth the investment.

Mr. ALVAREZ. May I make just a comment, please?

Mr. BEDELL. First, is it correct you would have less radioactive waste because of the fact it has lost some of its potency, or is that incorrect?

Mr. MORRISON. It shifts from being a highly radioactive material to having decayed to being considered as low-level radioactive waste.

Mr. ALVAREZ. I just wanted to make a comment about this.

Indeed, the Department of Energy is planning to lease its radiocesium. The last I read was about 12 cents a curie, maybe more or less. But that is about a factor of 10 less than the going market price for radiocobalt.

What happens when the stuff does leave the plant; where will it go? Presumably it will go back to Hanford.

The Energy Department is in the process of a major relaxation of its internal nuclear waste management standards so that these wastes could be disposed of in shallow burial pits. I consider this not to be an acceptable way of treating with radioactive waste.

The Hanford land base right now is being treated as a giant sponge; 137 billion gallons of radioactive wastes have been dumped right into the ground there and to just add more to that burden is not necessarily a beneficial use of a radioisotope.

Mr. BEDELL. I don't think you add to it, do you, because you have already got that. You have to get rid of it and it has been established it would have to be less potent, fewer rads.

Mr. ALVAREZ. I guess it is weighing the risk of transporting this on highways and run the risk of this spilling out on communities.

Mr. BEDELL. My time has expired.

Does anyone else have further questions? I have one or two yet.

In regard to India, you indicated there was some problem in India. Could you tell us what that is?

Ms. TUCKER. I was referring to a scientific study conducted in India where the researchers fed exactly the same diet to two groups of malnourished children. The title of the study is "Effects of Feeding Irradiated Wheat to Malnourished Children," conducted by Dr. Bhaskaram and Dr. Sadasivan.

Children received irradiated wheat that had been freshly irradiated. In other words, this wheat had not been stored for 1 or 2 years. It had been freshly irradiated.

The reasons the researchers were interested in this was because they have certain rules in India, but no storing grain because they previously had famines where many people died while the grain bibs were full. So they fed the freshly irradiated wheat to malnourished children and the malnourished children given the irradiated wheat developed blood and normalities.

Now, the researchers had not expected to have any problems. They thought this study would show that it was slightly safe to eat irradiated wheat. The levels at which the wheat was irradiated were under 100,000 rads.

Now, it is currently legal to irradiate wheat in the United States, but no one is doing it because it is too expensive to irradiate wheat.

There are viable options to preserving wheat. We believe that there are viable options to preserving our fresh fruits, vegetables, and grains that we should be pursuing instead of developing this hazardous technology.

Now, researchers, after finding these problems in the blood of children, instead of repeating it on other innocent victims, decided that they had better run some tests in the laboratory, and they fed freshly irradiated wheat to mice. They found the same kinds of blood abnormalities develop. They fed it to monkeys. They found the same kind of blood abnormalities.

They concluded that freshly irradiated wheat should not be fed to people.

Mr. BEDELL. A hundred thousand rads, is that what we are talking about?

Ms. TUCKER. This particular study used 75,000 rads, which is well under the proposed FDA levels.

Mr. BEDELL. 5,000 rads?

Mr. ALVAREZ. 75,000.

Ms. FROMPOVICH. Excuse me, sir. This study is in the information that I am putting into the record. It has been recited.

Mr. BEDELL. My question is, the FDA is going to approve 100. Is that 100,000 rads?

Ms. TUCKER. The FDA is proposing 100,000 rads, up to 100,000 rads. Anything under that would be allowable.

Mr. BEDELL. Thank you.

Mr. Roberts, do you have some questions?

Mr. ROBERTS. Yes, Mr. Chairman.

In the interest of the record here, I would like to ask in regard to the Indian study, I have a particular interest in this issue. When you mentioned wheat, my ears start to perk up.

We have about a billion eight in terms of carryover. We are going to have a lot of wheat on the ground out in my country and virtually all of it is going under loan. We have to have a means of storing it and preserving it. With the hearings over 18 months ago,

led by my colleague from California on the EDB situation, we have to have some alternatives.

There are a few chemicals left that are, say, in that category, but if I am any judge of public opinion or activities or the testimony that you have provided, I would guess that you would not be for those chemicals either. So we are taking a look at what would be possible, and as we go down the list to acceptable alternatives, I guess I look at this one as one we ought to take a good, hard look at.

Certainly I am not a part of any cabal from the nuclear waste industry in regards to why I have an interest in these hearings, or a plot or a conspiracy.

In regard to the Indian study, what was the sample size? The information I have here says that only 12 children were involved and it was done on malnourished children, and that these children are certainly more vulnerable to this particular blood disorder. Other studies were critical and then I have a laundry list of six different studies who refuted that study.

I am not saying it is wrong. I am just saying, this is the information I have along with your information.

How are we going to store all this wheat?

Ms. TUCKER. Congressman, I would like to make two points. First is that I, like you, was told that the Indian study had been refuted. I have yet to see a citation to a single scientific journal article refuting this study.

Second, I was told that——

Mr. ROBERTS. Wait 1 minute.

I have the Journal of Food and Cosmetics Toxology, 1976, technical report, series of International Project in the Area of Feed Irradiation, 1977, the Journal of Toxology, 1977, and a letter, the Journal of Food and Cosmetic Toxology, 1981, and the joint expert committee report of 1976.

Ms. TUCKER. We wrote to one of the scientists who was part of that joint committee report asking—because we had been told that he had said the study was fraudulent.

Our response from him was that, well, they had discounted the study because they said that about 4 percent of the general population is expected to have polyploids in their blood.

The study done on the children was a small number of children, thank goodness, and since it showed damaging effects. Now, it doesn't take a genius to figure out that if you have a study sample of 15 children, they added another five children to see if the stored wheat would also—if the stored irradiated wheat would have the same effects as the freshly irradiated wheat.

And so they had a total of 15 children and this particular researcher gave me the preposterous explanation that since one would expect to find 4 percent of the population to have polyploids in their blood and none of the control groups are polyploids in their groups there was something wrong with the study.

His explanation to me was not logical.

Mr. ROBERTS. That was one of the scientists that took part in this.

One of how many?

Ms. TUCKER. Yes. I would be happy to review the other citations which you give because I haven't seen those.

Mr. ROBERTS. I think that would be helpful for the subcommittee.

Ms. TUCKER. The director of the Institute also explained, no, he had not repudiated the study and gave us further information about why they had conducted the study in the first place.

I think this is the type of study that ought to be looked into in some American laboratories. What happens to the food that makes it different when it is freshly irradiated than when it has been stored for a long time?

Apparently we don't know. My second response is that especially for wheat we have a viable alternative that is not environmentally hazardous.

You see 100,000 rads of radiation does not sterilize the wheat. It merely either kills off the insects or inhibits their ability to reproduce.

By driving these insects of oxygen which can be done both in the fields or in the grain bins themselves we can achieve the same goal of killing off insects that might eat up the wheat.

I think that we ought to be pursuing these kinds of preservation technologies rather than promoting ultrahazardous technologies.

Mr. ROBERTS. I am not sure that is an economical alternative.

Ms. TUCKER. They are doing it in Europe and Asia.

Mr. ROBERTS. You people aren't going to be upset if I continue to eat beef jerky that has been dried by the sunlight in the same process, is it?

Ms. FROMPOVICH. That is your choice, sir.

May I have some input for 1 second, Mr. Roberts?

Mr. ROBERTS. Certainly, Doctor.

Ms. FROMPOVICH. We in the field know that there is a lot of subclinical nutrition in this country, especially in the ethnic groups, in the poor minorities and this is a place where we could probably see this same type thing happening.

Thank you.

Mr. ROBERTS. Thank you, Mr. Chairman.

Mr. ALVAREZ. I just want to add about the Indian study is this data was presented at the annual meeting of the American Nuclear Society in Washington, DC, last fall and much to our shock and surprise, the individuals who have conducted research in this field for the Government, U.S. Government on nuclear radiation said that the Indian study was fraudulently performed and that the National Institute of Nutrition declared it to be fraudulent.

This kind of ad hominem behavior, I think, is in violation of scientific freedom and responsibility. It is very hard to accept these kinds of—this kind of research, when these kinds of claims are made before important public forums. That is something that these folks should be held accountable to.

If you can't find something wrong with the merits, you shouldn't be lying about it in an ad hominem fashion and quite frankly, that is just what happened.

Mr. ROBERTS. I'm sorry. I yielded back my time, but one other consideration here.

When you say people lie, I suppose we ought to look into that. I am sure we ought to look into that in terms of that allegation, but

it is my understanding that the methodology was in question in 1981 again the Journal of Food Science article that criticized that study because the wheat was heat sterilized and it was their theory it was heat sterilization not the process that caused the problem.

Obviously we are not scientific experts that can make that kind of judgment, but I think we have clearly two different schools of opinion.

I appreciate your bringing this to our attention.

Mr. ALVAREZ. Sir, I just want to add the fact there is a debate over this very important study is an indication that there is a lack of consensus about food safety, and therefore I think from the point of view of public health, you don't make a major decision to serve irradiated food to thousands of people when there is no consensus.

Mr. BEDELL. Dr. Frompovich, you indicated that one of the problems was that there were no guidelines for radiation. I have to assume that if we move forward with it, the Department will certainly put out guidelines as to how this is to be performed.

Ms. FROMPOVICH. I don't think the guidelines can be manufactured in 1 week or 10 days or overnight, and with the way this food irradiation is being pushed through, I think we are going to have some of it on the market very soon, and therefore I think that should be taken into consideration.

No food should be on the market until there is——

Mr. BEDELL. You feel if they do move forward, there should be guidelines.

Ms. FROMPOVICH. Yes, sir, and specifically it should be marked.

Mr. ROBERTS. Can I please ask one other question, Mr. Chairman?

Mr. Alvarez, I get the feeling when I read the testimony of people who are extremely concerned about our policy in terms of food safety in this country, we are just in pretty bad shape, that the consumers choice and quality of the food product today in this country is something that if I could use some adjectives and adverbs from your testimony, I think it would be pretty grim to say the least.

Is that your feeling, we in this country, in terms of food safety, are on a perilous course and that the farmers' product and then after the middleman processes through here, when you walk in Safeway, Giant, or whatever, we are headed toward some real problems?

I am talking about a general statement now, not a specific thing in terms of this process.

Mr. ALVAREZ. Well, sir, I do not consider myself to be an expert on the safety of foods and what is being treated in foods.

However, in looking merely at the record of food irradiation, I think the credibility of this research is in question.

In particular, a good deal of the research done pertaining to safety food irradiation was done by an agency, a private corporation which was eventually indicted and whose chief executive officers were sent to prison for performing fraudulent research.

Mr. ROBERTS. I am not into that.

Mr. ALVAREZ. I understand, but the public is not into that and the public——

Mr. ROBERTS. If I might reclaim my time and ask for a specific answer to my general question, rather than a continued laundry list of accusations in regard to this particular thing, I would appreciate it.

I yield back, Mr. Chairman.

Mr. BEDELL. We had testimony that there are 21 countries that had already approved this. Are some of those major countries? Are you folks knowledgeable in that regard?

Ms. TUCKER. We do have lists back at our office of the countries that have approved food irradiation. By and large, they are for a small number of food items and they are approving them by food item and to our understanding, and we have been told this both by reporters and people within the industry, is that most countries are looking to see what the United States is going to do before they attempt vast commercialization.

I do understand that there is irradiated food now being served in South Africa, in the Netherlands, and in Japan. I am not certain of the status of food irradiation in countries like the U.S.S.R.

Mr. BEDELL. Do you know if there have been any problems in those countries where they have done this?

Ms. TUCKER. No; I do not. The types of problems we fear in terms of health are the kind that do not appear immediately. You do not eat a piece of irradiated food and drop dead. We are concerned about the long-term genetic problems and long-term potentials for diseases like cancer.

Ms. FROMPOVICH. Excuse me, Mr. Chairman. May I please address that question?

Mr. BEDELL. Yes.

Ms. FROMPOVICH. One of our colleagues who will be testifying later on this afternoon has some information that was just received from Great Britain about their decision on food irradiation which may be to the negative.

Mr. BEDELL. Thank you very much. We appreciate your testimony very much.

Our next panel will be Mr. Richard Graves, chairman, Government Relations Committee, United Fresh Fruit and Vegetable Association, Alexandria, VA; Dr. C. Donald Van Houweling, director of Government affairs, National Port Producers Council in Des Moines, IA; Lawrence T. Graham, executive vice president, public affairs, National Food Processors Association in Washington, DC; Dr. Harry C. Mussman, chairman, Coalition for Food Irradiation in Washington, DC.

We will add Dr. Harold Lubin, director, Department of Personal Health Program/Food and Nutrition, American Medical Association in Chicago, IL.

STATEMENT OF J. RICHARD GRAVES, JR., CHAIRMAN, GOVERNMENT RELATIONS COMMITTEE, UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Mr. GRAVES. Mr. Chairman, members of the subcommittee, I am Richard Graves of Graves Brothers Packing Co. in Wabasoo, FL. We grow and ship citrus products both domestically and overseas under the name of Indian River Citrus Sales.

I also am the chairman of the Government Relations Committee and past member of the board of directors of the United Fresh Fruit and Vegetable Association. United is the national trade association for the fresh produce industry. The 2,500 members include growers/shippers, wholesalers, retailers and affiliated industries from across the United States and 21 countries. United members handle 80 percent of the fresh produce commercially marketed in the United States.

On behalf of United, it is a pleasure for me to testify before the subcommittee today on the issue of food irradiation. United fully supports the development and research of food irradiation as one possible alternative to some postharvest treatments of fresh produce. Although not a panacea for treating all fresh produce commodities, irradiation does offer the possibility of improving the trade and marketing potential of fresh produce.

The produce industry has been severely hampered in meeting foreign quarantine regulations with the cancellation by the Environmental Protection Agency of ethylene dibromide, EDB, a postharvest fumigant used to disinfest certain commodities. Because of the cancellation of this important fumigant, the produce industry is interested in the improved import and export potential irradiation offers to produce, in particular papaya, mangos, and apples, among others. Although the industry is also interested in irradiating citrus, further research and development is needed to determine the correct dosage without injuring the product.

In August 1985, United conducted a survey of a portion of the membership on the potential use of food irradiation by the fresh produce industry. Although all respondents agreed that food irradiation would eventually impact the produce industry, that impact will not be immediate. As one member responded, "After we, the public, become better informed, food irradiation will be a part of our every day lives, and the agricultural and produce industries will change radically."

There are still many hurdles to overcome before food irradiation will be commercially used by the fresh fruit and vegetable industry. Some of these are: achieving appropriate dose levels for disinfestation and marketability; economic viability; handling and distribution procedures; and the most important, the education of consumers and the food industry.

United has undertaken several activities over the past couple of years to help educate our members. Articles on food irradiation have been published in our trade magazine, OUTLOOK; workshops on food irradiation have been held during our annual convention; and United has distributed white papers on food irradiation to the membership.

On the subject of the successful use of irradiation, United's survey respondents were primarily concerned about consumer acceptance of irradiated produce. Because of the necessity for consumer education on irradiation, United was one of the founding members of the Coalition for Food Irradiation. This coalition of food groups has been recognized as a credible source for information on irradiation and is conducting activities to inform the press, Government officials, and the general public.

I now would like to comment specifically on H.R. 696, the "Federal Food Irradiation Development and Control Act of 1985," introduced by Congressman Sid Morrison. United commends Mr. Morrison for taking the initiative in the U.S. Congress to bring this issue to the forefront. The most important issue I wish to address today is the issue of labeling produce at the retail level.

Although H.R. 696 changes the definition of food irradiation from an additive to a process, the bill retains FDA's authority to regulate it as an additive. That means that FDA has the authority to require mandatory labeling of irradiated produce at retail.

The produce industry understands the interest on the part of some consumers who may want to know that their produce has been irradiated.

However, there are several very practical problems that prohibit the accurate labeling of produce at the retail level, including the inherent quality of the perishability of produce, space limitations, misbranding, and enforcement.

Several suggestions have been made as to how irradiated produce may be labeled. One option offered is to place a sticker on each piece. Certainly there are machines which place stickers on such commodities as oranges, avocados, papaya or bananas. It is not feasible, however, to place stickers on individual mushrooms, brussel sprouts, asparagus stalks, and many other items.

Another suggestion is to place the shipping container with the appropriate labeling in view of the buyer. The amount of space that would be taken up by the shipping containers would severely limit the amount of produce that would be offered for sale, indirectly increasing the cost of the produce to the consumer.

Placing signs or cards in the proximity of the irradiated commodity is a third suggestion. Because produce managers constantly change the arrangement of the produce department, it would be extremely difficult to ensure that the sign is in the correct space. This easily could lead to misbranding of the product.

Maintaining pricing information in the produce department is a difficult task and exemplifies the burdens produce managers have with signing.

There are several potential misbranding dangers should produce be required to be labeled. Consumers purchase produce with their hands. They pick it up, feel it for ripeness, look for uniformity in color and in some cases smell it. It there are two bins of apples for example, one irradiated and one not irradiated, there is nothing to prevent the consumer from picking up an apple from the irradiated bin and mistakenly putting it back down in the nonirradiated bin. The retail establishment could be held legally liable for misbranding even though control is completely out of their hands. Further, a lack of packaging to label, since most produce is sold by piece unpackaged, a manner that is generally preferred by consumers and is different from some meat product irradiation of produce does not prevent a health problem, it only prevents the spread of unwanted exotic pests in produce.

For any law or regulation to be effective, it must be enforceable. Because of a lack of enforcement capability on the part of FDA and the unfairness of putting retailers into situations where they cannot control possible misbranding, United urges that H.R. 696 be

amended to exempt irradiated fruits and vegetables from the mandatory labeling at retail.

Instead, United recommends that irradiated produce be regulated just like other produce which has received a postharvest treatment by requiring labeling of the shipping containers. An inherent protection in labeling of the shipping containers will be the prevention of irradiating the commodity again, insuring that the produce has been treated within the safety limits established by the FDA.

In addition FDA and the appropriate State agencies will be able to endorse these regulations in the packing houses or irradiation facilities.

Mr. BEDELL. What is your time situation, Mr. Graves?

Mr. GRAVES. Fifteen seconds.

United urges the subcommittee to make this amendment to insure enforceability of possible regulations.

Thank you again for inviting me to testify. I would be happy to answer any questions you may have.

[The prepared statement of Mr. Graves appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much.

We will now hear from Dr. Van Houweling, of the Pork Producers Council.

STATEMENT OF C. DONALD VAN HOUWELING, STAFF CONSULTANT, NATIONAL PORK PRODUCERS COUNCIL

Mr. VAN HOUWELING. Mr. Chairman, members of the subcommittee, we appreciate very much this opportunity to testify at this hearing.

The National Pork Producers Council represents practically all the commercial pork producers of the country. Rather than read my statement, I will try to summarize it and submit the entire statement for the record.

Mr. BEDELL. Without objection, the entire statement of each of you will be entered in the record.

Mr. VAN HOUWELING. The NPPC's primary interest in radiation relates to trichinosis. Our delegates in 1982 adopted a resolution calling for the council to adopt a program to eliminate trichinosis from the pork supply. This led to the establishment of a task force which has become known as the trichinosis safe pork task force.

Trichinosis is only a minor public health problem. There are less than 100 cases of trichinosis reported annually, but we believe now we have the technology and this minor problem should be eliminated.

It has always been of concern to pork producers for another reason, because we believe it interferes with the demand for pork.

One of our surveys indicated that 25 percent of the consumers ate less pork because of their concern about trichinosis. The same survey showed that many of the people ate less pork because it had to be cooked so thoroughly and therefore became dry and less palatable. So we think there are real advantages to eliminating trichinosis from the pork supply.

The task force that I referred to, the trichinosis safe task force, began to look at methods that could be used for testing hogs to cer-

tify that the pork from those hogs was free and we have been able to get one test recognized.

Another one is nearly to be by the FSIS, but irradiation is also a consideration we have had from the outset.

The Department of Energy approached our task force early on and pointed out that there had been research done over the years to show very low levels of irradiation could make pork safe as far as trichinosis was concerned.

They have contributed to research that we conducted at the USDA. Part of the research is one of the reasons the FDA has approved the petition for the approval for the irradiation of pork.

There was additional work done at Iowa State University on the palatability of microbial population of pork subjected to irradiation. I am happy to say that work conclude there were no adverse effects. In fact, the taste of the pork seemed to improve with the storage up to 21 days.

Now we recognize that one of the important considerations is consumer acceptance of irradiation. For that reason, last winter we conducted a survey of consumers to determine what their attitude was in regard to irradiation.

Forty percent expressed a concern, but to put that in perspective, I should point out that there was a higher concern, 57 percent, in regard to chemical additives of chemicals used in the production of food.

There was a higher percentage concerned about diseases that could be contracted from food and there was also a concern about preservatives.

I have a more complete report of the results of that survey which was in one of our publications, which I would submit as part of the record.

Mr. BEDELL. Without objection.

Mr. VAN HOUWELING. As far as labeling is concerned, we believe products should be labeled. We believe the consumers have a right to know the product has been irradiated, and we believe that in time irradiation will be an added value to food.

For that reason, we favor radiation. The exact form we haven't decided, but we are inclined to think that a logo or symbol, as has been suggested, would be the ideal way to convey the message. This will require an educational program by the Government and industry to be effectively done.

We also recognize whether or not this radiation will be used by the meat industry is probably depending on two points. One, again, the acceptance of consumers of the irradiated product, and second, the economic feasibility of this process versus other methods of processing food or meat.

Now, specifically in regard to legislation, we would like to commend the introducers and the cosponsors for introducing this legislation. We certainly favor the general purpose of it.

We have two or three concerns.

One, in regard to the labeling the irradiation as a process, if the requirements for the approval of the process are as difficult to obtain as for a food additive, we are not sure what has been gained by labeling a process rather than a food additive.

There is no question in our mind that it is properly a process, but whether or not the requirements that have been suggested in the bill for the approval of the process might not be more than is required.

We also do not feel that the inclusion that has been referred to would have a particularly useful effect. Our concern is again that the agencies involved might defer some of their decisionmaking to the Commission and it might lead to further delay rather than accomplishing the purpose which the Commission is ostensibly established for.

We also believe that the section 5 on the leasing of nuclear byproducts could better be handled in another bill than in a food bill. We don't doubt that there is a need for this kind of legislative action, but we prefer to see that separated from this food bill.

Thank you. If there are any questions, I will be glad to answer them.

[The prepared statement of Mr. Van Houweling appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you, Dr. Van Houweling.

We will next hear from Mr. Graham.

STATEMENT OF LAWRENCE T. GRAHAM, EXECUTIVE VICE PRESIDENT, PUBLIC AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION

Mr. GRAHAM. Thank you, Mr. Chairman.

I have a longer statement also I would like submitted.

Mr. BEDELL. Without objection, your entire statement will be admitted into the record.

Mr. GRAHAM. I will try to summarize my summary to not repeat some points that have already been made.

I am Lawrence Graham, executive vice president, public affairs, National Food Processors Association. I am pleased to have this opportunity to testify.

NFPA is a scientific and technically based trade association that represents nearly 600 companies including most of the major food processing companies in the United States. Our members pack processed fruits, vegetables, meat, fish, and specialty products, including canned, frozen, aseptic, dehydrated, pickled, and other preserved food items.

Included in our membership are companies that manufacture packaging and processing equipment or provide supplies and services to the food processing industry. This association's diverse membership and scientific background have made our interest almost automatic in the potential for irradiation.

NFPA feels it has always been in the forefront of technological development in food matters and irradiation is just another logical area for us to explore.

It is our understanding in FDA's final proposal on the low dose of irradiation of fruits and vegetables, the final regulation will require the packaged fruits and vegetables included in the statement "treated with irradiation" on the label.

We have not opposed the labeling. We feel it is inevitable for consumer acceptance. We are just concerned the right message is conveyed on the label.

As you know, it has been mentioned here today within the past decade EPA has canceled and suspended the registrations of a significant number of valuable and widely used pesticides.

We believe that the judicial use of pesticides will continue to be essential to production of economical and wholesome food but these recent developments demonstrated need for increased efforts by both Government and private industry to develop safe and effective nonchemical pest controls.

NFPA and its members believe irradiation is one of the most promising alternatives to pesticides. I think it is important to remember that all new food processes were questioned extensively by consumers before acceptance and widespread use.

Canning, freezing, pasteurization, and microwaving were new technologies whose safety and efficiency were questioned. Consumer acceptance of irradiated food will also be an evolutionary process.

We believe that irradiation on the basis of FDA approval and increasing use will, like earlier processing technology, ultimately be viewed as safe, effective, and beneficial to consumers.

Although it is our understanding there is no intention to make any substantive change in section 409 of the Food, Drug and Cosmetic Act except to highlight that irradiation is not the same as other food additives, but rather is a process, the lengthy amendments to that section are cumbersome and could create confusion or lead to misinterpretation.

We think it would be simpler to leave section 409 untouched, particularly since section 201 of the act defines food additive to include any source of irradiation intended for such use.

We have other specific language changes in the bill which are included in my longer statement. But in any event, we believe that the bill would provide a soluable mechanism to promote irradiation research and development to foster greatly needed consumer education.

The legislation also promotes rational and consistent use of food irradiation and to reduce unwarranted burdens on commerce by preempting State and local food irradiation different than or different to those imposed by FDA.

An area of concern to the food processing industry is a negative reaction by the consumer to anything that maybe connected with nuclear power. For this reason, we question the appropriateness of section 59(a)(5) of H.R. 696 in what is in legislation promoting a new food processing technology. That section deals with the leasing of nuclear byproduct material.

The American Medical Association, the World Health Organization, the American Council on Science and Health have already endorsed irradiation as a safe food process.

The technology is already widely used in hospital facilities, especially for patients on immunosuppressive drugs who are required to have a diet free of microbiologic contamination.

We are also presently working with the Department of Energy on a cooperative agreement which would provide us a cesium agri-

culture commodities' irradiator which would be built next to our food research laboratory in Dublin, CA.

Our present laboratory facilities in California and Seattle and Washington, DC, enable us to do research in all types of food processing and packaging. A radiation facility next to our California lab would enable us to study the interaction between different types of food processing, for example, irradiation and thermal processing or irradiation and freezing—would also allow us to do sensory evaluation work and nutritional studies.

This demonstration project, as you know, was created by Congress as a way to assess the feasibility of this type of technology transfer.

DOE has said the use of radiation to treat foodstuffs would constitute an evolutionary process and could do much to reduce post-harvest losses of food, increase international trade potential, and eliminate health threatening micro-organisms in food.

We have not signed a final agreement with DOE but we are working with them toward that goal and we look forward to participating in food irradiation research.

We feel once they have developed a satisfactory agreement to irradiate fruits and vegetables, such a process will eventually become widespread.

Thank you very much.

[The prepared statement of Mr. Graham appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much, Mr. Graham.

We will next hear from Dr. Mussman.

STATEMENT OF HARRY C. MUSSMAN, EXECUTIVE VICE PRESIDENT, SCIENTIFIC AFFAIRS, NATIONAL FOOD PROCESSORS ASSOCIATION, AND CHAIRMAN, COALITION FOR FOOD IRRADIATION

Mr. MUSSMAN. Thank you, Mr. Chairman, members of the subcommittee.

On behalf of the Coalition for Food Irradiation, I would like to thank this subcommittee for the opportunity to appear before you and to present the views of the coalition regarding food irradiation technology and the consuming public.

The Coalition for Food Irradiation was created approximately 1 year ago at a time when the food industry realized, recognized, that there was not broad understanding on the part of the consumer of what this technology was all about and that in order for the irradiation of foods to take its place rightfully as part of the preservation technology available to the food processing industry and for which the consumers would benefit, that it would be necessary to bring to the consuming public bald, honest, credible information regarding this technology.

It was for that purpose that the coalition was formed and that has been essentially the mission of the coalition during the interim period to date.

We have submitted as part of our prepared testimony a copy of the white paper that we have put together as a coalition activity which has been widely distributed in an attempt to address many

of the current concerns which consumers have been raising from time to time in attempting to deal with them, as I said a moment ago, honestly, credibly, so that the consumers can be in a position to make a more informed understanding judgment.

The makeup of the coalition is trade associations and companies in the business of processing foods.

Some of the trade associations included in the Pork Producers Council from whom you have already heard, the American Meat Institute, the United Fresh Fruit & Vegetables Produce Marketing Association, others, plus a number of companies, something in excess of 20 major processing companies in the country who believe that the potential for food irradiation is such that it warrants making an effort to attempt to get the consumer to understand better what this technology is about.

No one wishes to simply hand this technology to the consuming public and expect them to accept it. I believe everyone understands that in order for them to accept it, they must be better informed about the technology itself.

The coalition's broad-based membership suggests a variety of ways in which irradiation could be employed by the food industry. The fresh fruit and vegetables and spice industries could use irradiation as an alternative to the many chemicals and pesticides used to treat and disinfest their crops.

The meat and poultry industries could use irradiation to eliminate micro-organizisms and parasites that cause disease.

Both of these are extremely highly regarded as tradeoffs that should be brought to the public's attention.

The processed food industry could employ the technology to either sterilize packaging materials or combine the treatment with other processes to develop new interpretations of nutrition foods for the American public.

The benefits of the process are many. We have already elaborated them, but I think they bear repeating.

Consumers will be able to buy products that stay fresher longer since the process can extend the shelf life. It can also retard mold and spoilage bacteria.

Despite existing health and safety standards and warnings to consumers about proper food handling, disease-carrying bacteria, such as salmonella, and parasites such as trichinae, harm a number of individuals each year.

Widespread use of irradiation could address these problems, not necessarily solving them completely, but certainly making a substantial impact on what the future of those diseases would be in this country.

I think the main points that I need to make regarding the coalition's message to the consumer are the following.

They address the individual concerns that have been raised by a number of consumer groups. One, irradiation does not make food radioactive.

Two, irradiation does not create harmful new substances in food and alter the nature of the food.

Three, irradiation does not create new strains of bacteria which become resistant at some future point.

Four, irradiation does not significantly alter the nutritional quality of foods, probably not any more than most other preservation methods might.

It is important to recognize that the food industry is conservative by nature and unwilling to jeopardize its relationship of trust with consumers by employing a controversial new technology. However, I think the food industry has made it abundantly clear they believe the potential of this technology is such that it warrants being given an opportunity to work.

Let me conclude, Mr. Chairman, with a commendation also as the others have of Congressman Morrison and the cosponsors of this bill H.R. 696.

We support as this coalition the general principles of the bill. We believe that it will do much to enhance the consumer education efforts which the coalition is undertaking.

We acknowledge that there are some flaws in it which others have already mentioned, but in a general sense, the coalition is fully supportive of this legislation as a step forward in having this technology accepted by the American public.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Mussman appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you, Dr. Mussman. Dr. Lubin.

STATEMENT OF A. HAROLD LUBIN, M.D., DIRECTOR, DEPARTMENT OF FOODS, NUTRITION, AND PERSONAL HEALTH, AMERICAN MEDICAL ASSOCIATION, ACCOMPANIED BY THOMAS WOLFF, DEPARTMENT OF FEDERAL LEGISLATION

Dr. LUBIN. Mr. Chairman and members of the subcommittee, my name is Harold Lubin, and I am director of the Department of Foods, Nutrition, and Personal Health of the American Medical Association. Accompanying me is Thomas Wolff of the AMA's Department of Federal Legislation. The AMA appreciates the invitation to testify today concerning H.R. 696, the Federal Food Irradiation Development and Control Act of 1985.

AMA supports H.R. 696. Many years of international experience have demonstrated that foods irradiated at levels of up to 10 kilograys, or 1,000 kilorads, are safe to eat. In fact, in 1980, the Joint Expert Committee on the Wholesomeness of Irradiated Foods concluded that "The irradiation of any food commodity up to an average dose of 10 kilograys presents no toxicological hazard" and "introduces no special nutritional or microbiological problems." The Codex Alimentarius Commission, a United Nations organization under the auspices of the WHO and the FAO, has recommended unconditional clearance for foods irradiated at a dose not exceeding 10 kGy, or 1,000 kilorads.

Food irradiation leaves no residue in food. Moreover, while food irradiation does cause slight chemical and physical changes in food, these changes are no more significant than the changes that occur from other accepted food processes such as boiling or freezing. Over 30 years of study using sophisticated analytical techniques to ascertain what unique radiolytic products [URP's] may be formed in ir-

radiated food have failed to detect the production of any URP's of toxicological concern.

Food irradiation produces no significant reduction in the nutritional quality of food. In addition, it has a number of important potential applications. Food irradiation is effective in killing the micro-organisms that cause food spoilage. Thus, food irradiation could extend the storage life of numerous perishable foods, thereby increasing the productivity of U.S. food processing and distribution and opening new export opportunities. These factors are very significant since a considerable amount of the world's food supply is lost each year through spoilage in the postharvest disinfestation of foods and vegetables.

Food irradiated may also be an alternative to pesticides by which health concerns have been raised. Moreover, it may be effective in controlling trichinae in fresh pork and salmonella in red meats, poultry, and fish.

In our view, formal official reclassification of food irradiation is important in terms of public acceptance of the fact that food irradiation is a safe process, not a potentially hazardous food additive. It is important to note that food irradiation does not make the irradiated food radioactive, since it is done at energy levels well below those required to induce radioactivity. We believe it is appropriate, however, that the bill would not eliminate the FDA's authority to regulate food irradiation. This would offer to the public assurance of continued protection.

The AMA supports the establishment of the Joint Operating Commission for Food Irradiation. The Commission would perform the vital function of coordinating research concerning food irradiation that currently is fragmented among many Federal agencies. The Commission would also have the important function of promoting public understanding and acceptance of food irradiation. This would entail informing the public of the many potential benefits of food irradiation and addressing any unwarranted concerns regarding the process.

Finally, we believe it is appropriate for the Commission to have the authority to petition the FDA if it believes that the commercial application of food irradiation should be expanded.

We also support the provision in the bill that would preempt State and local laws that are in addition to or different from the FDA's requirements concerning food irradiation. We believe that the regulation of food irradiation should be uniform throughout the country in order to ensure that the nationwide marketing of irradiated food is not impeded by inconsistent or conflicting State and local government requirements.

The AMA recognizes that questions must still be addressed concerning whether food irradiation will be a cost-effective process for some commercial applications. Moreover, additional educational efforts by the food industry, the Government, and health professionals may be needed to help ensure widespread consumer acceptance of the use of food irradiation. However, we believe that enactment of H.R. 696 is an important first step in promoting the use of the promising technology of food irradiation. We support early adoption of this legislation.

Mr. Chairman, the AMA appreciates your invitation to testify before the subcommittee and stands ready to work with you concerning this important issue.

[The prepared statement of Dr. Lubin appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you, Dr. Lubin.

Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

I have some comments for all of you, which we don't have time for. Let me start with Mr. Graves, on behalf of particularly the retailers that are members of your organization, you have a concern about misbranding of individual items acquired for labeling, is that accurate, and the impact that it might well have at retail levels?

Mr. GRAVES. I think the concern is that produce is constantly moved around in a produce department. Also the produce on the whole is not packaged. It is sold by piece, and it is very difficult to label individual pieces of produce, and it is also very difficult to keep signed placement above produce because of the movement of produce within the department to keep that in an accurate position.

Mr. MORRISON. And I suppose that is the reason why products that have been fumigated or treated in other ways currently under existing laws are not required for labeling at retail?

Mr. GRAVES. Yes. Of course, there are many processes in fresh produce that are applied during the conversion from the field condition to the packaged condition, and all of these processes are marked on the shipping container.

Mr. MORRISON. So that is available at the wholesale level, but it has never really been made a requirement as far as retail sales are concerned?

Mr. GRAVES. It is available to the retailer in that area. It is not available to the consumer at the final point of purchase.

Mr. MORRISON. Thank you.

Dr. Mussman, I guess more of an expression of appreciation than anything, because the coalition, I think, has put together an effective force, distribution of facts and figures, that I think are necessary, since all the surveys seem to point out that consumers like the product, they are a little concerned about it until they know something about it, and your coalition is making the effort to see that they do have facts upon which to base their opinions. I think that is most effective and will help all of the groups, so we appreciate that very much.

Do you have plans to expand now the distribution of a number of your materials for the sake of consumer education?

Mr. MUSSMAN. We are attempting to get them to any group or individual who may be expressing interest in knowing more about the technology. As you have said, there are a number of consumers, we estimate perhaps as many as half of the consuming public, are not very familiar with this technology. They have been conditioned for perhaps 30 years or more to be suspicious of anything with the word "irradiate" or "irradiation" attached to it, so it represents a significant challenge for the coalition to attempt to put into those people's hands the kind of information which permits

them to make a better informed judgment regarding whether they like or dislike the general idea.

We will indeed attempt to get the information that we are putting together more broadly disseminated than we have in the past.

Mr. MORRISON. Thank you.

Dr. Lubin, I appreciate the support of the American Medical Association, and know that you went through a rather lengthy procedure to reach that conclusion. One of the previous panels had some shots taken at the medical community, if you will, because of the change in attitude by doctors toward the use of x rays on expectant mothers, and they compared our knowledge of food irradiation now to the knowledge of medical fraternity back in the 1950's when they took x rays every time you turned around.

Could you refute that in any way? Don't we have a lot of research on irradiation that takes us well beyond that point?

Dr. LUBIN. Thank you for bringing that to light. One of the major difficulties is that often items are compared which are not comparable. First of all, I would emphasize that I think the information which was provided was oversimplified, and in fact I would appreciate the data that supports even the contention that many infants were damaged because of radiation exposure when their mothers were pregnant, but even if we took that at face value, which I think we cannot, it certainly does not bear any comparison with the issue at hand.

Furthermore, I think, as many people have pointed out, foods which are irradiated or ionized for protective and better purposes of improving the food supply prevent any kinds of danger at the doses that are being proposed. I think, in short, there is not a public safety hazard, and I can't emphasize that strongly enough.

Mr. MORRISON. You sort of underlined "at the doses proposed." Isn't that a significant factor? In effect, you can refute most of the negative aspects of the studies that have been quoted here this morning because they were at significantly higher level doses of treatment?

Dr. LUBIN. That is correct. I think we are aware, as the FDA pointed out, that they tend to work in a very conservative and measured concerned way for the interests of the public and safety. It at best would be 10 times less than the internationally accepted doses for many kinds of foodstuffs, and even that level has been a significant factor, less than many applications which have been utilized over at least 15 or 20 years, and for which there is no emergence of any adverse effects information at all.

Mr. MORRISON. Thank you very much. Thank you, Mr. Chairman.

Mr. BEDELL. Mr. Brown.

Mr. BROWN. Thank you, Mr. Chairman.

I find it reassuring that all of you gentlemen have been so firm in your presentations with regard to the safety of this process, and yet I am still equally concerned about the attitude of the consumers, and I am heartened by the fact that you seem to believe also in the importance of a consumer education program.

I think you are all well aware of the history of the introduction of new technologies in this country, where quite generally there is an attitude on the part of the established institutions seeking to in-

troduce this that it is obviously safe and we don't need to be concerned, and consumers have been disillusioned by this in the past. So it is very important that we conduct not only a full-scale research program, but a full-scale consumer education program.

Just speaking in very general terms, we have seen the development of nuclear energy and some of its processes which did not live up to the original touting of it. We have seen the widespread use of chemicals which turned out in many cases not to be as beneficial as we had hoped. We have seen in the early days of air pollution, for example, we were told not to worry, a little air pollution can't hurt you, and then the medical profession found out later that it did. These are things which are of concern to the American people, and we have to reassure them.

Now, there is one gap in all of the testimony this morning that bothers me a little, from those who are proponents of this, and that is not so much the food safety aspect but we have not really dealt with the problem of the widespread distribution of the radiation sources.

I am going to ask Dr. Lubin if you can comment as to whether or not there have not been cases where the widespread distribution of radioactive sources in medicine have actually, through carelessness, mistakes, and so forth, created hazards in some cases, and we have not dealt not only with the safety of the facility, but with the safety of the transportation process, which has been brought up by some of the groups. These, too, will need to be addressed in some realistic way, and I hope that all of you are aware of this and are giving some thought to it.

Would you comment, Dr. Lubin, with regard to the safety record of the use of radioactive sources in the health field, due to causes which we didn't anticipate or could not control, but nevertheless existed.

Dr. LUBIN. Congressman Brown, I would better serve you and the other members of the subcommittee if I indicated that I would be pleased to get available information to document what I believe to be the case. But not being a radiation expert, I would be more comfortable to provide that to you, so that anyone who questioned it would have something to go back to.

I think that it would be unfair and inappropriate to say that anything in the life in which we live is perfectly safe. I think in terms of relative risk and a great deal of benefit to the large segment of world and our own society, there is no question that the safety factor is not a significant or major one, and in fact probably is not the one that should really be focused upon for the public, and I would be pleased to have the opportunity to pursue that and get you that information.

Mr. BROWN. I think I probably agree with you on the overall results, but I still think we need the information, because our tactics should be not to say "trust us" to the public, but to provide evidence that we should be trusted.

Dr. LUBIN. I agree wholeheartedly.

Mr. BROWN. I am old enough to have been through a couple of generations of the use of x rays in health, for example. When I go to my dentist today, I get a lot more protection from x rays, and so

do the staff, than they did 10 or 20 years ago, and the reasons are they found that there are defective x ray machines.

There are all sorts of problems that we have gradually sought to correct over the years, and I think all of us know, and we now hope that we are a lot safer than we were 20 or 30 years ago. We would like to start out with that level of safety today in this area, and I think it will help us to get the consumer acceptance that is absolutely necessary, as all of you know, if this is to be successful.

Dr. LUBIN. I think the point you make is an excellent one, Congressman Brown. I would like to further emphasize that the introduction and utilization of this process by no means negates the need for careful hygiene, careful occupational safety efforts, and many of the things which we have learned through experience over years that are longer than any of us are old. I think it does, however, indicate that we need to take some strength and reassurance from that safety record, rather than being frightened from approaching new and advisable technologies that could be of a great deal of benefit.

Mr. BROWN. Thank you.

Mr. BEDELL. Thank you, Mr. Brown.

Dr. Lubin, apparently this has been used in hospitals fairly extensively; is that correct?

Dr. LUBIN. That is correct. I believe that Dr. Miller earlier indicated some experience in immunocompetent or immunocompromised individuals who may have taken for as long as 10 years up to 25 percent of their food intake on a daily basis which had been irradiated for their protection.

Mr. BEDELL. Do you know if there has been any indication of any problems with any of those?

Dr. LUBIN. To my knowledge there has not been. There is certainly no published information to that effect.

Mr. BEDELL. The United Nations apparently has done some work in this regard, you indicated in your testimony, I think?

Dr. LUBIN. That is correct.

Mr. BEDELL. What have they done, do you know? Have they done any research?

Dr. LUBIN. The joint expert committee I think reviewed periodically, going back to 1976, at intervals of approximately 3 years, and the last review of which I am familiar was in 1980, and published in 1981 all of the existent research data.

I think there is certainly more that is emerging, and we learned this morning that there may be even more than we could review, and all of those reviews generally indicate the safety, as we also learned efficacy has not been addressed as strenuously, and certainly there are questions which still require further research and answers.

Mr. BEDELL. Mr. Brown accurately pinpointed a problem, and that is there has been some concern expressed by previous witnesses as to whether or not this will be well accepted by consumers, because of some of the problems that have developed in the past where initially we did not think there were concerns. Apparently, this group is not concerned over that.

Dr. Van Houweling, I would assume that the previous panel we had would be reluctant to buy pork that had been irradiated, for example.

Mr. VAN HOUWELING. Congressman Bedell, one of the reasons we joined in the Coalition for Food Irradiation very early was we tried to get out correct information to consumers. I referred to a survey that we did. As I said, it shows that people are concerned, but they are concerned about a lot of other things about food safety, like chemicals and preservatives. We think it is largely a matter of education. There are concerns about the constituency or change in the food. Expert after expert says that you change food when you cook it, you freeze it, and you dry it as well, so we believe it is largely a matter of good consumer education of the facts.

Mr. BEDELL. And you believe that will come if it is approved with labeling, where information is given to them so they know what they are buying?

Mr. VAN HOUWELING. I think that is right. But we do think if it is commercially available, then there will be greater effort on the part of those companies to convey that information as well. They are not going to participate in this unless they see a market for the product.

Mr. BEDELL. Mr. Graves, I have a little bit of trouble with the objection to the labeling for consumers of fresh vegetables and so on. It would appear to me that consumers should have an opportunity to know what is put in what they buy, and I guess I have trouble believing that if chemicals are added, for example, that they should not also be properly labeled for the consumer.

And I do not agree with your statement, by the way, that it is too difficult, because they move vegetables around, for them to have a sign. It seems to me it should not be any great problem to list the chemicals. I have trouble with your argument.

Mr. GRAVES. Mr. Chairman, we agree that the consumer should know what the produce has been treated with, and the item that we are talking about here, we are not talking about a preservative or using irradiation as a preservative in the fresh fruit and vegetable industry. It will be used just to control exotic pests that occur in the fruit, like fruit flies. Mainly, in the State of Florida right now, for instance, the Carib fly. There is a very practical problem to labeling each piece of merchandise.

Mr. BEDELL. I understand that clearly enough but I do not understand the problem of having it where the consumer buys it. I would think the information should be available in regard to chemicals that are on the article as well. I do not accept your argument that since you move things from here to there you can't very well label them as to what they are. If you are going to label, for instance, it seems a pretty difficult argument.

Mr. GRAVES. Take citrus. It is produced in at least three different areas in the United States, and each of those areas have subareas and each of those subareas have different processes and use different chemicals of waxes, of soaps, of fungicides on the produce, and I am talking more in this instance specifically of citrus. If you have that produce in the average supermarket which might have the citrus from at least four or five or possibly six of those areas all in produce bins, how would you label each one of the individual bins

and say that the fruit, that a produce clerk actually put the fruit in the proper bin? That is the problem that we have, is that there are multiple processes.

Mr. BEDELL. Of course, you could always have trouble with a clerk putting something in the wrong bin, I don't argue with that. But I would argue that if you have three bins of apples, where you have got Jonathan apples and you have got delicious apples and so on, that the label or sign be required to state any additives that have been used on those apples that might be of health concern to people. I guess there is no point in arguing that, although I have trouble with it.

Mr. GRAVES. I think the main point is that the produce comes from so many different areas of the United States and from the world, and it is difficult to keep it each separate according to the district in which it was produced, because again I say the processes do vary from one district to another.

Mr. BEDELL. Are there any other questions?

If not, we thank you very much for your testimony, and the subcommittee will recess to reconvene at 2 o'clock this afternoon for the remaining testimony.

[Whereupon, at 12:20 p.m., the subcommittee recessed to 2 p.m. of the same day.]

AFTERNOON SESSION

Mr. BEDELL. The subcommittee will come to order.

Our next panel consists of Mr. Denis Mosgofian, Mr. Bernard Fensterwald, and Mr. Miller.

Unless there are any statements of any of the members of the subcommittee, we will hear from you first, Mr. Mosgofian.

STATEMENT OF DENIS MOSGOFIAN, COFOUNDER AND DIRECTOR, NATIONAL COALITION TO STOP FOOD IRRADIATION

Mr. MOSGOFIAN. Thank you very much.

I appreciate this opportunity on behalf of both the members of my union and the members of the National Coalition, for this opportunity to present testimony on this matter.

Before I do, may I introduce into the record letters that I just received from both Representative Barbara Boxer, and from Senator Alan Cranston, indicating their opposition to H.R. 696.

Mr. BEDELL. Without objection they will be entered in the record with your prepared statement.

Mr. MOSGOFIAN. Thank you very much.

My name is Denis Mosgofian. I am an occupational health instructor to the graphic communications industry, and a photolithographer by trade.

I represent the 3,500 members of my union, the Graphic Communications International Local 583, as well as the members of the National Coalition to Stop Food Irradiation, of which I am cofounder and director. It is our view that H.R. 696 is a deeply flawed piece of legislation.

It is flawed in its premises, its assumptions, and its intents. First, H.R. 696's assertion that "irradiation of food . . . is recognized by international authorities and the Department of Health and

Human Services as safe and wholesome," is neither proof of its safety nor sufficient grounds for this legislation.

Until recently, international authorities and HHS recognized DES, benectin, thalidimide, sulfites, and asbestos as safe and wholesome.

We now know better.

It is important to note that what is international to one body is national to another, and local to others. We are impressed by proofs of safety, and not by reference to authorities. At this point there is no firm proof of safety.

The second flawed presumption on which H.R. 696 sits is that "irradiation is a process, much like cooking in a microwave oven, boiling or freezing." This could not be further from the truth. Gamma radiation is not a cooking technique.

It is ionizing energy; boiling, freezing and microwaving are not. It is completely misleading to relate them.

Ionizing gamma radiation precedes cooking; it does not replace it. Gamma radiation's unique radiolytic products will be added to the varied hazards of cooking, and will increase the total toxic load peoples bodies must contend with today, and we must look at gamma radiation in the context of all the other treatments we apply to food.

We must remember that gamma radiation kills, by molecular disruption and free radical chemistry, in order to appreciate its distinction from other food treatments. It is what ionizing radiation does that matters. H.R. 696 glosses this over.

Gamma irradiation adds adulterative compounds to food which were not there originally. It was with this understanding that Congress adopted the 1958 additives amendment to the Food, Drug and Cosmetic Act, and explicitly included food irradiation in the food additive classification. H.R. 696 seeks to void that congressional intent by falsely declaring gamma radiation is like boiling, etc.

The legislative intent in H.R. 696 of changing food irradiation from "additive" classification to "process" is specifically to remove irradiated food from FDA rigorous scrutiny, testing requirements and labeling obligations stipulated by the 1958 additives amendment quite on the contrary to the testimony given earlier with respect to FDA still having authority over this. Authority is one thing, but what they would actually do is the other.

And the intent is then to provide the FDA with a foundation we believe and the impetus to confidentially continue their no-retail label rulemaking process through the Federal Register. H.R. 696 seeks to effectively take the FDA out of the picture.

I cannot emphasize enough honest labeling protects consumers' right to know and preserves our right to choose, or to say no. We have the right to say no, or yes; and that is what would be eliminated if there were not an explicit requirement that comes under the additives amendment for labeling.

In terms of "process"—baking, boiling, freezing—there is no FDA safety review, except as to poor sanitation for microbacterial contamination. It is irresponsible to endorse the institutionalizing of this casual procedure for ionizing radiation.

This is what H.R. 696 asks you to do. An additive to processes is the cornerstone of H.R. 696.

The burden of food safety responsibility rests with the Government, not the consumer. H.R. 696 would institutionalize irresponsibility in administrative food scrutiny and simultaneously limit citizen review of precluding State and local elected officials from establishing more stringent consumer protection than may be established by the proposed Joint Operating Commission for Food Irradiation.

I only have about 1 minute.

May I go ahead?

H.R. 696 fails by omission to spell out a single consumer protection, and in the same legislation seeks removal of existing protections by changing food irradiation to a process.

It appears to us, and this is the next point we think is critical, that H.R. 696 is designed to promote the Department of Energy byproducts utilization program proposal for nuclear waste management. This program is the promotion of a socially acceptable industry, which will warehouse America's nuclear waste, notwithstanding the proposal to also increase production of cobalt 60, at our two plants in Dickerson, MD, and Pleasanton, CA.

Food irradiation depends upon a network of food irradiating plants. These are proposed to each house 3 million curies or more of radioactive cesium-137 or cobalt-60.

Now H.R. 696's passage is needed, we believe, to open the door for this program.

As you can see this program for food irradiating facilities will promote the widespread proliferation of radioactive waste. This will increase the likelihood of irreversible radioactive contamination of our communities and highways from inevitable human error and accident, miscalculation and negligence, and de facto impossibility of permanently and perfectly containing radioactivity.

In conclusion, only a full technology assessment and environmental impact review of the ultrahazardous radiation will offer us a firm beginning point for determining the actual consequences of launching food irradiation, for once launced, the effects will be irrevocable. H.R. 696, in our review is dangerous in its intention and alarmingly irresponsible.

I urge you to reject it and food irradiation.

[The prepared statement of Mr. Mosgofian appears at the conclusion of the hearing.]

Mr. MOSGOFIAN. Now, in addition I have brought with me just as a sampling of the kind of consumer response that we have gathered in the central and northern California regions, a petition, for example, largely centered around salmonella, 1,013 signatures gathered in a couple of months by a group opposing food irradiation.

They asked me if I would be kind enough to submit them to you for the record. As well, I have a statement here which I may not read I understand, which is from a woman named Linda Dinelli, who is with the group Citizens Against a Radioactive Dublin and they are in battle with the Department of Energy and the National Food Processors Association over the placement of their cesium agricultural commodities, agricultural cesium irradiation demonstration facility.

She would like, on behalf of their organization and the citizens of Dublin, to have this letter introduced, as well, into the record.

Mr. BEDELL. Without objection they will both be entered in the record or held in the file.

[The letter appears at the conclusion of the hearing; the petitions are held in the committee files.]

Mr. MOSGOFIAN. One other person who was going to testify, Dr. Noel Sommer from Davis, his wife is ill and he was unable to leave the hospital, and I have two of his documents which I would like to include as well as part of the record.

I think you for this opportunity.

Mr. BEDELL. Without objection.

Mr. Fensterwald.

STATEMENT OF BERNARD FENSTERWALD III, LEGISLATIVE COUNSEL, NATIONAL NUTRITIONAL FOODS ASSOCIATION

Mr. FENSTERWALD. We appreciate the opportunity to testify before the House Agriculture subcommittee.

The National Nutritional Foods Association appreciates being given the opportunity, too.

We would appreciate the complete statement be admitted in the record.

Mr. BEDELL. The entire statements of all the witnesses will be introduced.

Mr. FENSTERWALD. The National Nutritional Foods Association is comprised of approximately 4,000 retailers, wholesalers, and manufacturers of natural foods; headquartered in Costa Mesa, CA. We are the voice of the health food industry, representing businesses in all 50 States, and the District of Columbia.

We will shortly celebrate our 50th anniversary, and recent surveys indicate 10 of 15 American consumers shop regularly at a health food store. The National Health Foods funds a complete science department including the full-time biochemist on staff.

This, plus the extensive research conducted by our manufacturer members over the last 50 years is also at the disposal of the subcommittee at your request. We believe that the public has the right to know the nature of its food supply and the steps taken to process it.

Its safety and wholesomeness must be kept as the upper most criteria in determining the food future of food irradiation.

For this reason we urge the Congress and the FDA to move slowly in its approval of food irradiation and to require the testing necessary to ensure its safety. As an adjunct to this fundamental concept we submit that any use of food irradiation must be disclosed to the public through proper labeling.

The association believes radiation has not been adequately studied to determine its safety. And the Second National Congress for Food Protection was held in May 1984 about ionizing radiation:

> As this process becomes important in the preparation of a particular food, studies should be undertaken on the possible formation of toxic compounds in that food and the effects on the processing on nutrient bioavailability. Particular attention should be directed to the possible formation of any previously unidentified compounds in that food and how they may affect food safety and nutrition.

We doubt that Mr. Olson's criteria have been fully met in the short period of time that has elapsed since he made that statement. In fact, safety testing of irradiated foods has produced over the years a number of conflicting results.

Discussions of these studies in detail is included in our written statement. Additional scientific studies have shown that irradiation can lead to the destruction of unsaturated fatty acids, which are required for the normal structural integrity and functioning of cellular membranes.

These studies used the fatty acids of fish oils as targets of irradiation. As the subcommittee is undoubtedly aware, dietary fish oil fatty acids have gained widespread attention, both in the scientific-health community and in the media, and research is currently underway into their application as protective agents against heart disease.

Ionized radiation damages living cells through radio-chemical reactions, many of which involve the production of radiolytic, highly reactive oxidizing agents. Therefore, antioxidants occurring naturally in foods undergoing irradiation are chemically consumed in reactions with these radiolytic products. Overall the amount of ascorbic acid, tocopherols (vitamin E), B-Carotene, other vitamins and minerals, and certain amino acids naturally contained in food will be reduced.

With or without such precautions, we face a significant reduction in protective materials which have been present in foods throughout evolutionary time if we allow for the wholesale irradiation of food.

One must conclude these protected materials have served a purpose in insulating humans from natural radiation and from naturally-occurring oxidative toxicants.

Why should we lower our actual defense at a time when environmental pollutants and carcinogens are on the rise?

Intensive scientific investigation and public interest is currently being given to these naturally-occurring protective agents against degenerative disease and some aspects of the aging process. Prudent diets emphasizing these agents have been recently recommended by a number of Government agencies, including the National Academy of Sciences, the National Cancer Institute, USDA, FDA, the American Cancer Society, and American Heart Association.

What these studies suggest is that while the right hand is making advances in the protection of society through enhanced nutrition, incredible as it may seem, the left hand is advocating the large-scale introduction of a food-processing technique which specifically destroys many of these protective nutrients.

The need for exact quantification of nutrient loss and for strict supervision of commercial irradiation procedures is apparent. The NNFA believes the continuous evaluation of irradiation and of the processing specifications and conditions are mandatory.

We doubt that extrapolation from the animal studies done to date, and from the limited use of irradiated foods by astronauts and cancer patients, can be used for accurate predictions of safety and nutritional adequacy by the entire diverse population of our

Nation, especially down the road 20 years when a large portion of our diet has been irradiated.

We have also strongly endorsed labeling of irradiated foods at point of sale. American consumers have a basic right to know what they are purchasing.

When they buy and use foods traded by canning, pasteurization, freezing, pickling, dehydration, salting, et cetera, they have a reasonable knowledge of how that food has been treated. There is no special reason that we are aware of that creates special treatment for irradiation and mandates that its use be kept secret.

If I could have about 1 minute I will be finished.

Mr. BEDELL. All right.

Mr. FENSTERWALD. For these reasons we oppose passage of H.R. 696. First, we believe the bill as presently drafted will play right into the hands of the nuclear industry which is the largest proponent of food irradiation who desire quick approval of the process for commercial use.

Rather we urge the Congress and the FDA to move cautiously and slowly because no one knows at this point what the long-term nutritional effect will be when large segments of our population eat irradiated foods as an expanded portion of their diet.

Second, we oppose H.R. 696 because: One, it will allow irradiated foods to be sold without proper labeling, and two, it will deny State and local authorities the opportunity to require labeling even if the FDA declines to do so. Quite frankly, Mr. Chairman, one has to question the motives of the proponents of this legislation who wish to ram it down the throats of the American public but they try to hide it from them at this time. This above all else is the outrage that must be avoided.

Again, Mr. Chairman, the NFAA appreciates the opportunity to testify today and if we can answer any questions we will be happy to do so.

[The prepared statement of Mr. Fensterwald appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you, Mr. Fensterwald.

Mr. Miller.

STATEMENT OF CLINTON RAY MILLER, LEGISLATIVE ADVOCATE, NATIONAL HEALTH FEDERATION

Mr. MILLER. Thank you very much, Mr. Chairman, and distinguished members of the subcommittee. We appreciate very much your allowing me to appear at this important hearing to offer comments and proposed amendments of the National Health Federation on H.R. 696.

We support wholeheartedly the testimony of all the people on the fourth panel today and the amendment specifically proposed by Mr. Robert Alvarez of the Environmental Policy Institute.

With my testimony, Mr. Chairman, I have six exhibits that I would like to have included in the record, if I could.

Mr. BEDELL. Without objection they will be entered in the record or held in the committee files.

Mr. MILLER. My name is Clinton Ray Miller. For 23 years I have been the legislative advocate for the National Health Federation.

NHF is a 30-year-old national consumer organization of responsible, aware, environmental, health, and fitness minded activists who take very seriously our mutual responsibility for the safety and wholesomeness of the food we eat.

We have learned by sad experience, Mr. Chairman, we cannot delegate this responsibility to State or Federal bureaucrats who are often on their way through what Merton Mintz of the Washington Post called a revolving door into or from high-paying jobs in the very industries they are supposed to regulate.

In 1962 we "fathered" and won virtual unanimous approval of NHF's "Human Guinea Pig Amendment" which, for the first time in recorded history, in any country specifically prevented any further medical experimentation on humans without their informed consent.

This NHF amendment has fundamentally changed the practice of medicine not only in the United States, but throughout the civilized world.

Now come the proponents of food irradiation and want us to participate in an unprecedented massive medical experiment without our knowledge and consent.

Members of the National Health Federation and increasingly millions of other individuals are deeply concerned that eating irradiated food is still in the experimental stage. NHF agrees with Dr. Sanford A. Miller, Director of the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition, who testified earlier here today. When asked if he felt irradiated foods should be labeled, he stated:

> Yes, I personally do. The Department may have another view on this—which they did, of course, at that time—and there actually are some good reason why you shouldn't have to do it. My own feelings are that it should be labeled, and when it is said and done, I think it will be.

The NHF is unalterably opposed to H.R. 696 [S. 288] in its present form. Unless it is drastically amended we will do all in our power to urge our thousands of members and millions of friends to kill this legislation.

NHF proposes the following amendments to H.R. 696:

One, we urge you to amend out all language in this bill which declares or implies in any way that it is U.S. policy that "Congress finds that irradiation of foods is * * * safe and wholesome." You will find that statement on page 2, lines 5 to 8 of the bill.

Congress may pass a law stating it is safe to buy, sell, transport, store, keep track of, use and dispose of the massive amounts of highly radioactive material which would be used in hundreds and possibly thousands of food irradiation plants—some of which would be located near or in our largest cities—but that doesn't make this terribly dangerous technology one bit safer than it really is.

Saying it is safe doesn't make it safe.

Congress can pass a law stating it finds the world is flat, but that doesn't bend the horizon one inch.

We therefore suggest for amendment No. 1: On page 2, strike out the present language on lines 5 to 8 and in its place insert wording somewhat as follows:

> Sec. 2(a). The Congress finds that: (1) irradiation of food is a relatively new food preservation technology compared with drying, freezing and canning. The hazards

or safety of consuming irradiated foods for long periods of time covering several generations is simply not known.

The technology itself is extremely hazardous even if the irradiated food is found to be absolutely safe. The transportation, storage, use, and disposal of radioactive material is the most hazardous technology yet used to preserve food.

Amendment No. 2: We suggest you delete all language from the bill which would remove food irradiation from the current statutory requirements it be regulated by FDA as a "food additive."

After hearing the testimony today we think there should be a third amendment that would require mandatory prison terms for any irradiation plant which exceeds the limits imposed by FDA.

Thank you, Mr. Chairman.

[The prepared statement of Mr. Miller appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you very much, Mr. Miller.

Mr. Brown.

Mr. BROWN. I have no questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

Mr. Mosgofian, you took generally some hard shots at irradiation facilities. Would you close down the medical facilities that exist in the country?

Mr. MOSGOFIAN. No; But I don't think they are related. It is sort of a little bit like relating space ships and apples. They are not the same thing.

Mr. MORRISON. They are the same plants. I have been through the plants that are radiating medical supplies at the same time they have done some good.

Mr. MOSGOFIAN. You are talking about the irradiation facility that irradiate medical supplies.

Mr. MORRISON. Right.

Mr. MOSGOFIAN. The distinction we want to draw—actually I am concerned to some extent about them and how much they would proliferate. At this point there seems to be some vagueness as to the number of independent irradiating facilities in the United States.

That is not to say they aren't hazardous. The one in Tucson which had to be shut down by the Governor of Arizona, or the one in Dover, NJ, the cleanup of which was just finished at a cost that was probably at least half again as the initial cost to put it in are illustrations of the kind of safety and track record as well as the kind of community contamination hazard that is opposed from residents in those areas.

That has nothing to do with what they were doing with either the tridium, or the cobalt 60 in either of those two instances.

The situation we are dealing with and the ones that the people that I represent are concerned about are one, not only the effects on the food which is a whole category into its public health hazard and long-term medical hazard but second, the possibility of, in fact, the actual fact of proliferating our waste supply of throughout both America and the developing world as the proponents of this idea are talking.

If that happens that is irreversible. Whether you and I like irradiation is irrelevant. That is irreversible phenomenon and once that takes place there would be nobody around to basically turn that back so we can say 20 years from now well, that was a mistake.

Now, let's clean it up. We can't even clean up effectively Three Mile Island. There is still raging controversy around that one facility that had that major accident.

Mr. MORRISON. That is totally different. You talk about comparing things. In the same Three Mile Island there the reaction makes other things radioactive. In the case of the irradiation of food or medical supplies there is no way anything can become radioactive.

Mr. MOSGOFIAN. That is not the issue.

Mr. MORRISON. The issue I am addressing.

Mr. MOSGOFIAN. I thought you asked me if I would shut down and I can't understand it. At first I thought you were talking about hospitals.

You were talking about those irradiators which, in fact, irradiate medical supplies such as sutures and medical supplies, is that right?

Mr. MORRISON. Yes.

Mr. MOSGOFIAN. I said the question here is the hazard that is opposed from both proliferation and contamination and part of that is not addressed in your question.

I am concerned about those two things just as we should be concerned because we actually have a track record that shows that irradiators are hazardous facilities.

This is a ultrahazardous industry. It is not a game and it needs to be treated as such. H.R. 696 does not recognize that, particularly in light of the attempt to even take the food portion out from underneath additives classification which requires FDA rigorous scrutiny labeling and put it in a more benign classification of process.

The facility in Dover, NJ that had that spill, that had the 5,700 liters or gallons of internal spill, the external spill, over a year it has taken to clean that facility up, the situation in Tucson, AZ, with urine samples of children and mothers in that school district coming up with a high level of tritium in the urine.

I can't manufacture that and that is not something we should brush aside. I have a quote here.

Mr. MORRISON. Why don't you just answer the question. Would you like to close all these facilities?

Mr. MOSGOFIAN. I would close any facility that poses any hazard to any community they reside in; yes.

Mr. MORRISON. You are saying they could properly regulate it to be safe indeed?

Mr. MOSGOFIAN. I am not convinced at this point and I don't know very many people who are convinced that, in fact, it is possible to properly control contamination from radioactive materials. I don't see, in fact—I do think we should be very careful about the distinction between food irradiation which has another whole component and radiation of medical supplies.

It appears to me that politically, ride the tails of irradiating medical supplies and squeeze food in under the door is——

Mr. MORRISON. If I can reclaim my time.

I am not asking the question for that reason but you are taking some very hard shots, all of you on this panel, at irradiation facilities themselves.

I visited a few of them and I don't see it as an ultrahazardous industry if the radioisotopes or the source materials are properly handled just like any other industry.

Mr. MOSGOFIAN. I don't see where the track record shows they have ever been properly handled.

Mr. MORRISON. I think there are a number of firms around this country and they probably all in all have a relatively good record compared with other industries.

One other point. I realize I am out of time.

You indicate in your testimony the legislative intent of H.R. 696 changing it from an additive to process is to remove it from scrutiny.

I wrote the bill and I can't find that anywhere. It certainly wasn't my intent, and yet you, in your letter, are declaring this is the legislative intent.

This was not to remove it from anybody's scrutiny, and it is very carefully written that way so it leaves it totally in the hands of the Food and Drug Administration just as if it was an additive, but changes from this term additive, which it is not, to a process which it is.

Mr. MOSGOFIAN. May I respond to that?

Mr. MORRISON. Certainly.

Mr. MOSGOFIAN. It is an additive precisely why it was put in the 1958 amendment. It does create additional compounds and there is no way to avoid that. That is what the controversy around this is all about.

Mr. MORRISON. Does any process not change the product in some way?

Mr. MOSGOFIAN. It is not the same as microwaving, freezing, or boiling, or baking. None of those ionize. The difference between gamma radiation and microwave utilization is the outer electro rings in the target tissue are disrupted momentarily and new compounds are created.

It is precisely those new compounds which are the center of this issue. Those are called the unique radiolytic compounds. They are particularly hazardous when what we have is electrotoxins or insecticides, and fertilizers that are left in food will in fact be targeted by gamma radiation.

The result will be a whole new category of unknown or unique electrolytic products. The toxicity in long-term consumption has never been established. It is impossible to say at this point what the consequences will be.

We know just with respect to, say, a drug like thalidomide, we have a statement right here from the William S. Merrill Co. executive who said, "We have firmly established the safety dosage and usefulness of Kafadon, which is the brand name of thalidomide by both foreign and U.S. laboratory in clinical studies in the 1960's." We know what happened there.

Mr. MORRISON. How long do you think it would take before we could establish something you would be comfortable with?

Mr. MOSGOFIAN. Dr. John Govenan, radiation physicist and author of the book "Radiation and Human Health," has said that it would take a long-term study of a large population, perhaps 200,000 people, perhaps 50,000 people for a period of at least 30 years in order to determine the overall effects, but there are other methods that can be used which could at least give us a glimpse, for example, into the biological availability of the nutrient profile after it has been gamma radiated.

If you take a substance, and I am not a trained biochemist, I am working with trained people but I am myself—suffice it to say, I am sure you aren't either.

Mr. MORRISON. Perhaps since I am out of time, we will just say the 20 some countries in Europe that have approved it, we will get some sort of reading out of those areas within a reasonable amount of time.

Thank you, Mr. Chairman. I appreciate the extra time.

Mr. MILLER. Could I just get a clarification on this one point of food additive from the Congressman?

If you wrote the bill, I have looked at the Food, Drug and Cosmetic Act, under chapter 4 and I find 11 sections, none of which have to do with food processing.

Section 409 takes it from food additives but I don't see where it is going to go under food processing.

Which section would it be under? If we take it from food additives, where in the Food, Drug and Cosmetic Act do we regulate it under food processing?

Mr. MORRISON. You will find a number of sections in the bill that under food processing, under the section of food irradiation processing, so it plugs it right back into 409.

The letter which is part of the record from the Food and Drug Administration says this does not diminish our authority at all.

Mr. MILLER. I don't understand how we are going to regulate it as food processing if there is no section in here that regulates food processing.

Mr. MORRISON. It is in the bill.

Mr. MILLER. I was unable to find it; that is why I asked for clarification.

Mr. MOSGOFIAN. It is actual bill itself? I have the bill.

Mr. MILLER. There is no new section if we are going to regulate food processing. I think we should regulate food processing and I think your idea, Congressman, is excellent.

I think we should relook at all food processing. I think we ought to add a section 412 and put it—food processing. This is the place it ought to be and then define food processing so, we who are interested in consumer protection, can know what FDA's jurisdiction is on food processing. This would cover cooking. This would cover canning. These things that have been said that this is no more harmful than maybe it is time we relooked at pasturization and cooking and canning under a section on food processing.

Mr. MORRISON. I will certainly join you on the concept of relative risk because I think we should be looking at all these procedures and doing some comparison and I get the feeling irradiation would come out probably looking rather well.

Thank you, Mr. Chairman.

Mr. MOSGOFIAN. Mr. Chairman, I would like to make one brief comment.

In Britain currently, unless it has been changed within the last 5 or 6 days, irradiation of food is both banned for domestic consumption as well as for export. In Germany, while it is OK for export, it is illegal for domestic consumption.

When international authorities are referred to, it is our belief that what is international to us is national to someone else, maybe local to someone else.

I am not impressed by that. I don't think we should be impressed by international authorities. I think we need to look at the actual evidence.

Mr. BEDELL. We have been joined by the chairman of our full committee. Mr. de la Garza, did you have any statements or questions at all? We appreciate your joining us.

The CHAIRMAN. No thank you, Mr. Chairman.

Mr. BEDELL. Fine. Mr. Mosgofian, can you tell me what happened in England in regard to that situation?

Mr. MOSGOFIAN. No. I have a document called "Food Irradiation in Britain?" published in September 1985. We are in touch with the London Food Commission, but I can't tell you why the British Government made it illegal. I do know, however, they put it into a category called novel and irradiated foods.

So it was in the first place put there. That may have been for historical purposes. I don't know why they have banned it but they have.

[The publication entitled "Food Irradiation in Britain?" appears at the conclusion of the hearing.]

Mr. BEDELL. Where are they irradiating food in Britan?

Mr. MOSGOFIAN. I don't know, Mr. Chairman. I will be glad to find that information out for you.

Mr. BEDELL. I think it is something that would be of interest to the subcommittee. We are trying to learn all we can about this issue. I hope you understand the situation that exists on the subcommittee. We have testimony from the Government people that tell us they cannot detect any difference in food that has been irradiated.

Apparently it has been used extensively in hospitals. Apparently the United Nations says that it is a satisfactory process. Apparently a number of countries are doing this. Apparently it has been used as I understand it in the Army with no detrimental effects. So we have all of this testimony then we have some groups coming forth, and I don't question your sincerity for one minute, coming forth saying that they think this is a dangerous procedure. I think we also have to, at least speaking for myself, say there are two things we have to consider.

One is that we have done things that looked safe, but we found out later they were not. On the other hand, there are people and groups that are always resistant to any change.

We understand those things fully on the subcommittee, but I can assure you that in my opinion the subcommittee members are seriously trying to understand this issue and trying to do what would appear to be in the best interest of our country and people.

The real documentation of problems appears to me to be fairly limited. Now that doesn't mean there may not be problems. I understand your concern but except for what occurred in India which is apparently somewhat questionable and some of these studies which I again think are subject to question, I don't know that we have very much documentation one way or another to indicate this is harmful to the people who eat the products.

Mr. MOSGOFIAN. That is actually an interesting point, Mr. Chairman. It would then point to the conclusion that the appropriate beginning point for Congress is a full technology assessment, an environmental impact study which would then give us absolute solid ground presuming that the study was done to a protocol or design that would answer the appropriate questions.

It would give us a place to stand on and say we now have the specific documentation. I am not convinced for example, that the Indian study showed anything more than a specific chromosonal damage result which needs to be further studied.

The aflotoxin toxin studies, the studies which reveal aflotoxin toxin, probably the second most feared toxin in food, is enhanced in its lethalness after gamma radiation. I am not convinced that doesn't need to be thoroughly examined or those studies should be trusted to their face.

It is the case for example, that one strain of the spores of the constrictium botulism which is the most feared toxin in food actually is given a free reign in the ecology after gamma radiation because the gamma radiation essentially wipes out everything else.

I think in fact what we have all be presented with, and I have been working on this for some time probably since March 1984 when I first heard about the fruits and vegetables ruling, is that there has been a mixing of sales hyperbole on behalf of those folks, those industry people and government people who are interested in promoting this industry and mixed that up with the kind of evidence that is necessary to establish something which has the consequences that this has.

I would rather have done something else over the last 2 years of my life but I felt the consequences of this were so grave I didn't have any choice either for myself or my children or their children.

When we look at the FDA paper that was published in 1968 by the FDA when they banned the radiation of pork that the Army had been given permission to do from 1963 to 1968, we see that the FDA's own paper indicates that there were such adverse effects, health effects that they could no longer consider it safe or wise to allow or give permission for the irradiation of that canned bacon and other pork products and the Army withdrew its next petition for canned ham.

Until July 22, 1985, just 3 days before the new EPA ruling would have gone into effect, the FDA had not allowed any irradiation of pork products and has certainly answered such questions as what is going to happen to the very fatty pork tissue in lithium production which is a known carcinogen or any effects that are in the FDA's own literature.

I am not making this up. This was published in 1968. None of the material in here has been shown in any long-term study to be proven beyond the question of a doubt it no longer is valid.

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Why was the science not valid at that point? I have a serious question and that is—I am sure you do too—why is there an attempt to continually minimize those negative effects which have been shown and at the same time and negate them almost orally and each time they get rereviewed as one writer in the FDA said it appears they disappear until those negative effects no longer have a reality.

Mr. BEDELL. Of course, I think probably we have some questionable health effects on all the different ways we try to preserve food, whether we do it through chemicals or something else. There is some cause for concern, I think. I think we make every effort to try to minimize that concern, and I guess I would also feel that we can't really ignore the testimony of the American Medical Association. Do you disagree with that?

Mr. MOSGOFIAN. I do but——

Mr. BEDELL. Why should the American Medical——

Mr. MOSGOFIAN. The American Medical Society, even the person himself, has said he has not examined all of the data basis that has been used to determine the conclusions that, for example, have been—that were drawn by the joint committee, the joint commission on food irradiation.

Mr. BEDELL. I say why would they have any prejudice? I know of no reason they would want to change one process or another.

Mr. MILLER. Could I address that, Mr. Chairman?

Mr. BEDELL. I can understand why the Atomic Energy Commission might, or somebody of that nature, but I don't see why the American Medical Association would have any reason to favor or oppose one process over another. Did you have something to add?

Mr. MILLER. I want to state briefly I remember very clearly the American Medical Association giving the same kind of approval to DES, diethylstilbestrol, in the production of chicken and animals.

In fact they said we could safely implant it in the ear of beef cattle. They said we could put it in the necks of chickens and they believed it was so safe they gave it to women to prevent miscarriage. Then the AMA had to back off when it realized that thousands of the female children of those women given DES were showing up with vaginal cancer. They told the women they had given this drug, this "safe" drug that it was "absolutely safe" with the same assurances they have told you they know of no adverse side effects to eating irradiated food.

Now even then the Food and Drug Administration did not ban DES. It wasn't until an oversight congressional committee of this Congress headed by Representative Fountain, who, unfortunately, has left us, insisted FDA look at the hard evidence that diethylstilbestrol was causing cancer that the Food and Drug Administration and AMA reluctantly and begrudgingly admitted what they had done. It was too late when they found out there were thousands and thousands of women who gave vaginal cancer to their daughters. AMA doctors administered DES and with the same safety assurances they have stated here apply to irradiated food. I am certain they didn't have any bad motives.

It is just they have bad science. They just say, let's rush into this with the whole country and then let's apologize after we are there. "Shoot from the hip and amend it in the record." You can do that

in Congress, but you can't do it with the lives of people. The AMA has a bad, bad track record. All the way from the Dalcon Shield to DES to Oraflex to Mer. 29 to Bendectin. It wasn't until Congress through the magnificent Fountain committee held hearings that the AMA or FDA ever withdrew these hazardous drugs from the marketplace.

The AMA has begrudgingly stopped using every single drug they have withdrawn only under constant oversight hearings of Congress. I think the rapidly declining membership of the AMA shows how much they represent the people. They are down now to 45 percent of the medical doctors that even belong to them. Twenty-three years ago, when I first came to lobby Congress they had 70 percent. At the rate they are going in another 45 years nobody will belong to them, and they shouldn't. They have lost credibility.

Mr. BEDELL. It is good to have you say that about somebody else other than the Congress of the United States.

Mr. MILLER. The Congress has done a good job, sir. The Congress has done a magnificent job.

Mr. BEDELL. Thank you very much. Are there any further questions?

If not, we appreciate your testimony very much. Thank you.

Mr. MILLER. Thank you.

Mr. BEDELL. Our next panel consists of Dr. William Marion, Institute of Food Technologists and the Council on Agricultural Science and Technology, Ames, IA, and Dr. Ari Brynjolfsson, Council on Agricultural Science and Technology at Ames, IA.

We will hear from you first, Dr. Marion. Again, we would ask you to hold your testimony to no more than 5 minutes.

STATEMENT OF WILLIAM W. MARION, EXECUTIVE VICE PRESIDENT, COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

Mr. MARION. Thank you very much, Congressman Bedell, Congressman de la Garza, other distinguished gentlemen. My name is William Marion. I serve as executive vice president of CAST, which is the Council for Agricultural Science and Technology, based in Ames, IA. In addition, I do cochair the Committee on Research for the Institute of Food Technologists. The latter is a scientific society representing some 25,000 to 26,000 food scientists and food technologists in academia, government, and industry.

Thank you for the invitation to appear before you this afternoon, and to comment on H.R. 696. I commend you for the efforts that have gone into this bill. Both CAST and IFT have published documents in the field of food processing previously. CAST presently has a major task force underway—and I regret that I don't have those documents in front of me today—that has a major task force underway on the topic of irradiation. The first of the two publications, "Wholesomeness of Food Treated with Ionizing Energy," has been written and is in the review process today. It should be published within a month or so.

A second paper on applications will be published some time in early 1986. Dr. Brynjolfsson, who is here with me, is a member of that task force.

It has been said on a number of occasions that there have been no totally new food processing technologies developed in the twentieth century. Many refinements in the long-established processes of canning, drying, freezing, curing, and fermenting have been made. The previous speakers referred to the use of microwave energy. It has become very common in home cookery. The use of ionizing radiation can become an option for a new and valuable food processing technique.

Low-level irradiation of food offers several advantages. It will greatly extend the shelf life of perishable foods such as strawberries. Pork, which contributes significantly to the nutrition of most Americans, is sometimes viewed with suspicion by consumers who fear trichina infection. The incidence of trichinosis infection in humans is very low indeed—30 cases in 1983; 95 in 1982.

Nevertheless, the U.S. Department of Agriculture and other advisory groups correctly point out that pork should be cooked to a well-done stage. That implies internal temperatures of 165 to 170 degrees Fahrenheit. Actually, trichina are inactivated at much lower temperatures—138 to 145 degrees Fahrenheit, but in choosing to be safe, consumers eliminate the use of pork in a number of traditional European recipes.

The use of irradiation to inactivate the few trinchia that may be present could have a positive effect on pork consumption, likewise it could do a great deal with the use of the surplus grain supply that is produced here in the United States, and likewise it would have a very positive effect on processing and marketing activities associated with the pork industry.

Mr. Chairman, I make my remarks in very brief form. I wish to say, in closing, the passage of H.R. 696 opens the door for a useful and safe food processing technique.

Now it is my pleasure, sir, to introduce Dr. Ari Brynjolfsson, sir, a physicist from Natick Laboratories.

[The prepared statement of Mr. Marion appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Dr. Brynjolfsson.

STATEMENT OF ARI BRYNJOLFSSON, MEMBER, SCIENTIFIC TASK FORCE ON WHOLESOMENESS OF FOODS TREATED WITH IONIZING ENERGY, COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY

Mr. BRYNJOLFSSON. Mr. Chairman, my name is Ari Brynjolfsson. From 1972 to 1980 I was Director of the U.S. National Food Irradiation Program, conducted by the U.S. Department of Army at the Natick Laboratories in Massachusetts. I appreciate the opportunity to present to you the statement on findings of the task force on wholesomeness of foods treated with ionizing energy, organized by the Council for Agricultural Science and Technology, CAST, as we call it.

A list of task force members is attached as enclosure 1 with this statement. I have the full text of the statement with me, and I will make that available for the record here. I have also several other documents that I would like to submit for the record. I have my

paper related to the subject, and I have another paper that was presented in 1980 but is still credible, and I have a report, "Wholesomeness of Irradiated Food" by the Joint Expert Committee in 1981, which I think would be nice to have for the record, so that people could see it.

Mr. BEDELL. Without objection, it will be entered in the record or held in the committee files.

Mr. BRYNJOLFSSON. And then I have three reports here which I think go heavily into the documentation of the safety. This is on the toxicological evaluation of irradiation in food. They are difficult to come by, so I make them available for the record here.

Mr. BEDELL. They will also be entered in the record without objection.

Mr. BRYNJOLFSSON. I also have here this recommendation.

Mr. BEDELL. I am not sure any of us understand what is in the report, but we will enter them in the record anyway.

Mr. BRYNJOLFSSON. I will report on the major findings of the CAST committee or the task force. The major findings of analysis were as follows:

(A) It appears proven with reasonable certainty that foods irradiated with doses up to an average dose of 58 kilogray are safe and wholesome. This conclusion is based on two principally different approaches:

(a) The analyses and toxicological evaluation of the radiolytic products; (b) the extensive animal feeding studies.

(B) The effect of irradiation on the nutrition are insignificant or comparable with other currently accepted food treatments.

(C) The irradiation does not introduce any special microbiological problem. Like any other method of food professing, it requires adherence to high hygienic standards and sound food microbiological principles.

(D) No induced activity is produced in the food when the proposed sources are used.

From these findings, we may conclude that:

The process of preserving food by irradiation up to an average dose of 58 kilogray accordingly should be recognized as safe and wholesome. Irradiation, like other processes for preserving the food for public consumption, requires adherence to high hygienic standards and sound principles in processing, storing, and distribution of the food.

FDA and/or USDA should accordingly inspect and approve the irradiation facilities for processing and control of the foods, and like in other federally inspected plants keep surveillance to assure adherence to good manufacturing principles for the benefit of the consumer. Present standards and regulations for treatment of nonirradiated foods, such as standard hygienic manufacturing practices, can be expanded and applied also to irradiated foods.

FDA and USDA should be permitted to set more stringent standards for design and operation of irradiation facilities for processing of food than those that NRC has set for design and operation of irradiation facilities used for processing of nonfood items.

The Codex Alimentarius, the international general standard for irradiated foods in international trade, forms a reasonable frame-

work for regulating and processing not only for international trade but also for trade within the country.

Mr. BEDELL. Dr. Brynjolfsson, how much more time do you need?

Mr. BRYNJOLFSSON. About a minute and a half.

Mr. BEDELL. Fine, you may go ahead.

Mr. BRYNJOLFSSON. These standards could with simple modification be applied to foods treated with sterilizing doses. Likewise, the Codex "International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods" forms a framework and provides guidelines for operating the irradiation plants for processing of foods.

Mr. Chairman, there are a few other comments that I would like to make which focus more directly on the bill. Under the heading "Findings and Purposes" on page 2 we have in the paragraph section 2(a)(2) the words "and eliminates trichnosis in pork." I think this is human trichinosis from eating trichine pork, so we should replace trichnosis by trichina, the word trichina. I would, however, prefer to have it "it eliminates parasites such as Toxoplasma gondii in meats" because I think we should remember that there are other parasites and elements in foods and in meats, Toxoplasma gondii, for example, which is very common in meats. About 25 percent of the population in the United States have antigens, and this causes birth defects and malformation in children. Very low doses of irradation could eliminate that.

I believe also that in another section we could make some changes referring to how we charge for assistance. I feel it would leave more flexibility if it would be easier for the universities and other institutions of that kind to get cobalt at lower cost, and would not have to charge at the current rate.

Finally, I worked for establishing the existing Subcommittee on Interagency on Radiation Research and Policy Coordination of the Federal Coordinating Council for Science Engineering and Technology, and I believe that might be a better forum for coordinating food irradiation work than the committee that is suggested in the bill.

This is just for your consideration. I think the bill is very good as it is. Thank you, Mr. Chairman.

[The prepared statement of Mr. Brynjolfsson appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you. Any questions, Mr. de la Garza or Mr. Roberts.

Mr. ROBERTS. Thank you, Mr. Chairman. I must admit to the same state of confusion that my chairman has as to the relative safety of this process. I have heard from earlier panel members that I should eat my beef jerky in Dodge City, KS, at my own risk, and I am not too sure, Mr. Morrison, whether I should eat this apple or not. On the one hand, I have the AMA and CAST telling me this will keep the doctor away, and on the other, that if I bite into this I will be like Eve and open up Pandora's box of original sin in terms of gene mutation.

I note very few members of the press have eaten one.

Mr. BEDELL. If the gentleman will yield, I have already had one and I am just as mean as ever.

Mr. ROBERTS. I think this is the dilemma we face. We have some very fine testimony from you here, doctor, saying that unquestionably this is safe and wholesome, and we have just the opposite 180 degrees away, black is black and white is white, from a collection of folks who believe very strongly that that is the case.

Does CAST have any research in regard to the irradiation of wheat? Because we had a case study, now, a very tragic case, over in India, and I asked some of the other panels. Are you conducting research in regards to this process of preserving wheat?

Mr. BRYNJOLFSSON. No. We are not conducting research at CAST.

Mr. ROBERTS. Are you aware?

Mr. BRYNJOLFSSON. Oh, yes. We are aware of the Indian study. We are very much aware of them.

Mr. ROBERTS. Do you have a summary of that? Is your conclusion such that we should be more careful and look into this situation with the report of the India situation, or is it something that you would still say is wholesome?

Mr. BRYNJOLFSSON. Yes, I addressed that in my paper that I submitted for the record, but let me here mention a few facts as I see it. This question, of course, has been a primary focus for a great many years. It has been brought up again and again, and again and again we have looked at the question to see if there was any point that we should investigate further. What I am talking about is the question of possible mutagenicity of eating irradiated foods. It was raised in 1957, it was raised in 1962, it was raised in 1966, it was raised again and again, and every time when the scientists looked at it, they could not find anything.

The India studies are on very few individuals. The statistical data do not support any conclusion whatsoever. The best that they can do is to raise suspicion. Because they raise suspicion, this was principally a good laboratory that did the studies, the National Institutes of Health in Heidelberg. Therefore, it was looked at very, very closely in India under the auspices of international processors, and of course many similar kinds of studies were done in the United States, and they all came out that there was nothing to support the suspicion.

These studies were of course very well-known to the Expert Committee in Geneva, the Expert Committee under the World Health Organization auspices.

Mr. ROBERTS. Do you agree with this, Dr. Marion? Is that your conclusion as well?

Mr. MARION. This is our conclusion. I would hope in this case that we could distinguish, and it may be very difficult in the short time, to talk about a body of literature. We wish, as representatives of CAST, to speak about the introduction of low-level irradiation and its potential impact in many areas in food processing.

If one were to go back to some of the very early literature of the fifties, and look at some of the very high dosage used, then one can imagine other things occurring, but it is our general feeling based on the summary of the best literature—and I must say when the study appears within a month or so we will have been as exhaustive as we can in a survey of worldwide literature—and it is our impression that a summary of that literature says we are speaking about a safe process, if used within measurable limits, sustainable

measurable limits, and we feel we are talking on the best data that we can find in the world today.

Mr. ROBERTS. I appreciate that. Thank you for the time, Mr. Chairman.

Mr. BENELL. Mr. Brown.

Mr. BROWN. Gentlemen, I suppose you would both agree that there is no way we can ever be absolutely certain that anything we do is going to be free from risk; am I correct in that?

Mr. MARION. I do agree with you, sir.

Mr. BROWN. Some of the previous witnesses have indicated that we do need to make much more extensive technology assessments. They have suggested long-term studies on large populations of humans, which is not the normal way we conduct studies of the risk of many kinds of drugs or other things of that sort. I suspect it would be impossible to do that if there was any possibility that there would be an endangering of human lives.

Do you feel that there is any course of action which could be taken in the way of a more systematic technology assessment or risk assessment that would end all of the speculation on this or bring us to a higher degree of certainty about this, something that hasn't been done yet?

Mr. BRYNJOLFSSON. You raise a very important question, and I am very happy to have the opportunity to elaborate on it. Animal experiments are not extremely sensitive, but they are extremely relevant. They are about the best that we have, especially when the animals are mammals, so we thought is there any way that we could do better than those animals experiments, which we can never be happy with, because of course we should be safe. We must be sure that it is safe. So what did we do?

We used absolutely the best technology to analyze the radiolytic programs that are formed in the food. We went to the best experts in this country and universities and wherever we could find them that have the best instruments to do that kind of experiment, and we took those data, collected them, analyzed them, and looked at the chemistry that was behind those data. We brought those data to a completely independent group of toxicologists that are used to evaluating the chemicals. They looked at them after the public evaluation that I have submitted for the record. They could not find any reason to doubt that irradiated foods were wholesome.

The chemical compounds that are produced are in the order of parts per billion, and we have hundreds of them. Those chemical compounds are usually commonly found in food. Actually, we have not found any compounds that are not commonly found in food, processed or unprocessed food. We have failed to find any chemical or radiolytic product that is not already in the food or that is in similar foods.

In addition, those chemicals that are produced by the irradiated products are in small quantities, and we have not found any that would indicate to us that they could be harmful to humans, and therefore these people put their scientific name on the line saying there is nothing to be concerned about.

Mr. BROWN. That is a very strong statement. Do you know of any studies that have been made on a somewhat different basis of the risk? I am thinking here of an overall comparison of the risk of the

present system of food processing versus the risk of processing through irradiation or versus the risk of some other new technology that we haven't looked at, chemical treatment or whatever, so that we could assure the public that there are risks even to the present system, there are risks from eating unprocessed foods without any treatment. There are risks from treating food by irradiation. There are risks of treating food with chemicals, bleaching agents or whatever, so that we could, for the purposes of public enlightenment get across the idea that we live in an environment that always has risks, but the risk in this area is different, no different or less than it would be if we did not make this kind of a change.

Mr. BRYNJOLFSSON. Mr. Chairman, that was one of our difficulties, that we were in many ways, when we were doing those studies, breaking new roads, roads that were not there before. We had to research what is, for instance, a good control for comparison. Are frozen foods better controlled than the heat-processed foods, because all those processes may produce some chemical compounds, and principally if you want to kill the bacteria, you must cause chemical processes.

In many cases it was not well known before we started, so part of our work was to in a way see what is there before we irradiate the food. What we found is that many of those products, when we are making it so sensitive and looking for such small quantities, that they are in the food, they are ubiquitous in the food and in the environment, and what we in a way find, for instance, that actually the chemical processes that are produced by the irradiation are much fewer and in smaller quantities than are produced by most other processes, like heat processing.

Mr. MARION. If I might add, Congressman Brown, the era we are in in the 1980's offers us the best analytical techniques we have ever known in the history of the world, and we all know that there is a certain amount of risk associated with our food supply, riding in a taxi or with other things, and yet at the same time we put a great deal of confidence in the pasteurization of milk.

Just the other day in the Chicago area, we had a major error occurring in a well-known pasteurization process, and yet, based on the best analytical techniques that can be employed today in the 1980's, low-level irradiation of food appears to be safe. It is not an absolutely guarantee, but it appears to us to be safe.

Mr. BROWN. We respect that point of view, but I am looking at this from the standpoint of how we reassure the American public, and they are actually skeptical of assurances today, and with every right because we have had assurances in the past that didn't live up to the billings, so I am looking for simple ways that we can do it.

Take the example of wheat as one. We could take wheat and not subject it to any kind of treatment. We could take it and irradiate it, or we can take it as I think we experimented with, and subject it to some sort of an inert gas, which by depriving oxygen to the organisms serves the same purpose.

There are probably hazards or risks to be associated with each one of these processes. Is there any way we could look at them and say what is the comparative risk between these three approaches

to trying to improve the quality of a particular food product for human consumption, and that could be a fairly involved comparison, I understand? I am just asking for information that these kinds of analyses have been made.

Mr. MARION. Toxicologists are spending a great deal of time on the question of assessment of risk, and it is difficult, but I am happy to say tests are improving in the assessment of risk, and yet it is going to be rather difficult right now to compare a process such as irradiation to, say, heat sterilization, but one does the best one can, at least in searching for certain products that are known to be harmful, if they are present in such-and-such amounts, and so that approach has been used extensively, and yet not one of us would say that we are dealing with something that is an absolutely safe one, and yet I would submit to you, sir, that in the study that is forthcoming from CAST, we have attempted to look at all toxicological data and experimental data on a very wide basis for clues of this sort.

Unfortunately, that is about all I can offer at the moment here in terms of questions on risk.

Mr. BROWN. We will look forward to seeing that study. The subject of trying to structure an adequate framework for risk analysis, risk assessment, is one that we have grappled with on a broader basis here in the Congress, and we recognize that we do not yet have a conceptual framework which allows us to do this in a completely satisfactory way, and we are hoping that as we move through each of these important areas, such as irradiation, we can broaden our knowledge of how to improve that process as we do it.

Thank you. I have no further questions.

Mr. BEDELL. Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

I notice, Dr. Brynjolfsson, that in your information—let me just read a sentence or two. "During the last 37 years, the effect of irradiation on the wholesomeness of food has been studied more thoroughly than that of any other processing of foods," and that in 1965, they issued the statements, "Foods irradiated up to absorbed doses of 5.6 megarads" of cobalt and so forth "have been found to be wholesome, that is, safe, and nutritionally adequate." That was later expanded to move it up to 10 kilorads.

I wanted to point out to those not familiar with the numbers and that is 58 to 100 times the level being proposed as safe by the Food and Drug Administration.

Is my mathematics accurate, Doctor?

Mr. BRYNJOLFSSON. Yes, it is correct.

Mr. MORRISON. So they have built in a most significant safety factor even from these some 37 years of experiments that were part of the United States Government work?

Mr. BRYNJOLFSSON. Yes, and let me also make it clear that these data, the safety factor, using a safety factor of 100, they built it in for 58 kilogray, so these data support that even 58 kilogray is safe with that margin of safety that is used for other processes, so when we are talking about one kilogray, we are factoring 100 and factoring 58; 5,800 above the use level.

Mr. MORRISON. Thank you.

I also want to point out that we do have a little bit of time limit as far as the astronauts and the fact that they have been eating food that has been sterilized through irradiation for a number of years.

Dr. Marion, I wanted to mention an appreciation to CAST for a number of things that they do, but one of the recent things I enjoyed reading was an analysis of a number of natural foods that do not come under the jurisdiction of the Food and Drug Administration, because there are no additives, there is no process, and yet they have toxicity that would frighten a number of people in this room that have testified on irradiation.

Do you have any observations on that analysis, including our favorite, carrots?

Mr. MARION. In many other foods, as you point out, sir, there are natural toxicants present, and obviously neither we nor other great bodies of thinkers can do anything about that, because they have built in, those have been built in over many years of evolution within those products. Certainly with regard to potatoes, with regard to just a wide number of products that are naturally produced, there are a number of toxicant substances that are formed. Casaba, which is not well known to us in this country except for a limited number of products from it, has very high levels of toxic substances in it, and one has learned to either eat those food products in relatively low amounts, small amounts, or there have been certain processing techniques that have adjusted after a fashion the toxicity, but we are dealing with that, and it simply says that in all probability, the safety of the irradiation process that you are identifying here, we are dealing with greater safety than we would be dealing with with the toxicants present in a number of our natural foods.

Mr. MORRISON. Thank you.

Thank you, Mr. Chairman.

Mr. BEDELL. Thank you, Mr. Morrison.

Dr. Brynjolfsson, you indicated that you were involved in this experiment that was done by the Army; is that correct?

Mr. BRYNJOLFSSON. Yes.

Mr. BEDELL. Previous witnesses have indicated that that was called off because of problems that they encountered with people who had eaten the food; is that correct?

Mr. BRYNJOLFSSON. Called off because of?

Mr. BEDELL. Previous witnesses have indicated that the Army experimented with this process for several years and I thought you were involved in that effort.

Mr. BRYNJOLFSSON. Yes.

Mr. BEDELL. And apparently they found there were problems with the people who ate the food that had been so processed, and therefore they stopped the experiment. Is that accurate?

Mr. BRYNJOLFSSON. No, no; no, sir. The only test subjects were exposed, testers would eat the irradiated food, except in the fifties there were a few experiments with humans, and there were no adverse effects found when those humans were exposed to irradiated food or had irradiated food, 100 percent of irradiated foods for an extended time. There were no adverse effects. These are scientific reports well documented. There can be no question about it.

Mr. BEDELL. I thought the previous witnesses indicated that there had been problems, and therefore, that the Army had stopped irradiation because it had caused health problems among those people who had eaten the irradiated food.

Mr. BRYNJOLFSSON. No; no, sir. That must be a complete misunderstanding.

Mr. BEDELL. There were no health problems of any of the soldiers that had eaten irradiated foods?

Mr. BRYNJOLFSSON. That is right. The reason that the Army transferred the program to the U.S. Department of Agriculture was only because they felt this was not their mission to develop new food processes. They felt that it was more properly placed with a civilian agency, and it had nothing to do with that not being good for the Army. The Army will use it when industry produces it.

Mr. BEDELL. We have also had previous testimony that indicated this process could cause the aflatoxin to be in greater concentrations and cause greater problems. Are you acquainted with that?

Mr. BRYNJOLFSSON. Yes, of course, we would look into things like that. The statistics that the witness was referring to were some Indian studies, and this was done with cooked food, on cooked food, where they had destroyed all the antifungal activity in the food before they put the fungi into the food. It has nothing to do with the real world where we would, for instance, irradiate the foods, the vegetables or the potatoes, because they items have antifungal activities in them, built in them, and the experiment as reported here is based on misunderstand completely of what it was about.

Mr. BEDELL. That experiment you say was conducted on food that had already been cooked, is that what you are saying?

Mr. BRYNJOLFSSON. Yes; that is right.

Mr. BEDELL. And normally this process would be applied to uncooked food; is that what you are saying?

Mr. BRYNJOLFSSON. Yes, cooking destroys the antifungal activity, so if you cook the food and then put the micro-organisms into it, it has nothing to do with radiation. They would grow better in that food.

Mr. BEDELL. The previous witnesses have also testified that irradiation changes the chemistry of the food in a technical way, and we don't know how or what the effects might be of those chemicals that would therefore be in the food as a result of irradiation, if I understood their testimony correctly.

Mr. BRYNJOLFSSON. Yes.

Mr. BEDELL. It affected part of the molecules somehow.

Mr. BRYNJOLFSSON. Yes, that could be said. There are some chemicals. Actually, I would say the shortcoming of food irradiation is more in a line that it does not inhibit some of the chemical reactions that will break the food down, because irradiation does not, for instance, inactivate enzymes, so that food will get soft and the texture will soften in the food because the irradiation does not inhibit those enzymes, but food technologies, they know these kinds of limitations. They are faced with them all the time. Also in the case of nonirradiated foods, so they must try to develop processes that stabilize the food. The chemical changes that are caused by irradiation are otherwise extremely small.

Mr. BEDELL. I guess the thing I am trying to understand myself is—if I might have another minute or two.

Mr. MORRISON. Please, Mr. Chairman.

Mr. BEDELL. If the radiation changes the composition of the food so that it, in effect, creates new chemicals in the food by changing some of the chemical composition of the food, the question is, are those chemicals that were created by the irradiation potentially harmful to the health of individuals.

Mr. BRYNJOLFSSON. Yes.

Mr. BEDELL. We need to try to understand this.

Mr. BRYNJOLFSSON. Every process will cause some chemical reactions, and what we have found is that the chemical changes caused by irradiation are relatively smaller than in most other processes.

But to then look at those chemical compounds that are formed in the food when we irradiate it, that is what we did in these studies which was then given to the toxicologist to study for irradiation—if these chemical substances that might be formed by irradiation, that we could see they were formed and that we also said might be formed, if they could be harmful.

And the toxicologist came out and said no, they couldn't be harmful.

Mr. MORRISON. Mr. Chairman, if you would yield on that point just for a moment, I recalled your earlier comments, doctor, you said you then went through these chemicals which had been created by the irradiation process and found that, in fact, they also occurred naturally in food.

In other words, there was nothing new as far as the chemical compounds that were created are concerned.

Mr. BRYNJOLFSSON. Yes, that is right.

Mr. MORRISON. You felt fairly comfortable with the supposed by-products of which we have heard so much.

Mr. BRYNJOLFSSON. Yes.

Mr. BEDELL. Do you have any knowledge at all about what has happened in Great Britain as to why they apparently have put a prohibition on the irradiation of food?

Mr. BRYNJOLFSSON. Great Britain has produced a great many scientists in this field, but they closed down everyone there about in 1962, mainly because they felt that they were not really in the food business and did not need it.

They have then been using it only in the case of hospital patients and for animal feed, and that is still permitted, but nothing has been permitted otherwise, principally waiting on the United States and other countries to clear it for them.

Mr. BEDELL. The testimony we had, I thought, indicated that Great Britain had been permitting irradiation in some instances and were now prohibiting it.

Is that accurate or inaccurate?

Mr. BRYNJOLFSSON. That is a misunderstanding by the man that testified.

Mr. BEDELL. This is not the case. They have just never permitted some of these things and still are not permitting them.

Mr. BRYNJOLFSSON. That is right. That does not mean that the health authorities there don't think that food irradiation is safe.

It is just that they do not want to create confusion, I would call it, where some people still—because they are not well-informed—still think that it may not be safe, and that is the reason they have not permitted it.

Mr. BEDELL. Do you have anything further?

Thank you very much for your testimony.

Our last panel consists of Mr. Jack Ransohoff, Neutron Products, Inc., of Dickerson, MD, and Ms. Marjorie Hecht, Fusion Energy Foundation of Leesburg, VA.

Mr. Ransohoff, since you are first on the list, we will have you go first.

Again, we would ask you to try and hold your testimony to no more than 5 minutes.

STATEMENT OF JACK RANSOHOFF, NEUTRON PRODUCTS, INC., DICKERSON, MD

Mr. RANSOHOFF. Thank you very much for inviting me to testify.

I would like to start out by answering Congressman Brown's question that he asked 15 or 20 minutes ago.

I think there are some things that you can do to make this comparison of risks that would be very simple and enlightening. Many opponents of radiation processing have been critical, have expressed concern over the hazards of shipping.

It would be a relatively simple matter to compare the hazards of shipping radioisotopes to radiation processing plants which occurs very seldom and has had a very good safety record over the years with the frequent shipping of ethylene oxide or ethylene dibromide or whatever chemical would be used for a comparable purpose.

The active chemicals that would be used in treating foods instead of radiation will not simply materialize on the site nor will they be used without hazard.

I think it would be a very simple matter to compare the safety of transportation and safety in the work place with the shipment and use of radioactive materials with the shipment and use of toxic chemicals.

Similarly, one could compare the effect of radiation on the food with the effect on the food of toxic chemicals that might be used as an alternative.

In the case of pepper, for example, there is a specification on the maximum permissable concentration of epichlorohydrin.

Epichlorohydrin does not occur naturally in pepper. It is a reaction product that occurs when you use ethylene oxide to sterilize pepper or to pasteurize it.

And so it goes. There are many comparisons that can be made, and I think it is an excellent suggestion. I think it is something that could be done and could be quantified.

There has been a great deal of time and effort expended in this hearing, asking the question as to whether or not there are, in fact, any new products that are produced by the irradiation of foods.

Without being able to name any, I can assure you that there are. The use of ionizing radiation is a very energetic process. It is going to produce new products. All foods are polymers, and you will get

cross linking. You will get chain situations. You will get all kinds of effects occurring. You can rely on it.

I think that you would do well to avoid the use of the concept of zero. Zero is a tentative thing, and zero will, in every case—will someday be replaced by a number as our ability to measure and detect improves.

I think you would be well advised to avoid a witch hunt for by-product chemicals. There will be some. I am sure that some will be different. There may be some to which people are allergic.

The fact remains that the use of radiation in the processing of food does not produce large quantities of byproducts, and so far, we are not aware of any that has caused the FDA to set a specification on the number of deleterious byproducts that are produced.

So much for the answer to Mr. Brown's question.

We have a couple of comments that we would like to make. Before making them, I would like to assure you I am not an anti-nuke. I have been in the nuclear business for nearly 35 years.

My livelihood depends on it. I have devoted my life to it, and I am for the use of radiation in every place it occurs.

Neutron Products is the second largest producer of radioactive sources in the world, and we are one of the larger users of radioactive sources.

We have two irradiators at Dickerson. I would like to invite you to come out and look at the operation sometime if you wish.

We are unalterably in favor of labeling. It really doesn't make any difference what the details are. People have a right to know whether or not food has been irradiated simply because they want to know.

Someday, they may not care, but until that day comes, I think the cause of irradiated food will be well served by requiring labeling.

It really doesn't make any difference how small the food product is. In the case of a papaya or a mango or a grapefruit, the individual fruit can be labeled.

In the case of asparagus or strawberries or something like that, it would be a relatively simple matter to package the food and have a label on the package.

As long as people care, as long as people are interested, we think they have a right to know whether or not their food has been irradiated. And if they aren't advised, then I think you are going to get suspicion and misinformation, and that will be much worse than labeling.

So that those people who do not wish to eat irradiated food can buy some other food that is processed by some other means.

The concept that Government promotion is required or desirable, I think, is a bad one. We have been irradiating spices in truckload quantities. The principal obstacle to the wider irradiation of spices is simply that many spice processors feel that their needs are well served by existing processes or past processes, and some spice manufacturers are working on new processes, not radiation processes that they believe they will favor.

So, our experience has been that if the regulations permit it, and if the processes are viable, food irradiation will naturally take its place.

It does not need Government intervention. It does not need Government support.

To the contrary, we believe very strongly that the issues become confused by Government support. We think the cause of food irradiation is best served if the Government will serve the role of a disinterested regulator that is concerned about food safety, obviously concerned about food safety, and only concerned about food safety.

Mr. BEDELL. I made everybody else hold pretty well to 5 minutes. What is your time situation, Mr. Ransohoff?

Mr. RANSOHOFF. Could I have a couple more minutes?

Mr. BEDELL. Without objection.

Mr. RANSOHOFF. We think that if the Government has two roles—one as a governmental agency, one as a regulator—it would confuse the public.

We think the public should rely on the Government being a disinterested bystander.

In that regard, I would like to say we have—back to shipping for 1 minute—we have been, over the last 20 years, we have made more than 1,000 shipments of high level radioactive material shipments covering a distance of more than 1 million miles and containing more than 30 million curies of cobalt-60.

We have never had an accident. We have never had a problem. The rules regarding the shipment of radioactive materials are very strict.

That doesn't mean there won't be some mistakes, and that doesn't mean it isn't hazardous, but the record has been pretty good so far.

In addition, although there have been some accidents that have been belabored here in the operation of radiation processing plants, the record overall has been very good.

We have one very, very serious concern with regard to this bill. Cobalt-60 is a tough metal. It is corrosion resistant, and if used in massive form, it is very resistant to dispersion.

Cobalt 60-sources are also made of pellets. Therefore, in the case of a source failure, you do have cobalt in a dispersible form.

That is the form it was used in the facility in Georgia that everybody has heard about.

That was the form that was in the cancer therapy source that became world famous when it was stolen from a warehouse in Juarez.

We think that radioactive sources that contain radioactive material in an easily dispersible form should not be used, should not be encouraged.

Although cesium could be in a form that is dispersion resistant, cesium chloride is a very soluble, easily dispersible form.

It is being heavily subsidized now, and we think it is a very, very poor choice. I would like to, at some point, some other time—it will take much more time than this, and I really would rather do it in closed session.

I would like to be heard in closed session on the permits of using cesium. I think it is a very serious mistake, and I think it could really discredit the NRC, the DOE, and the Congress.

Thank you.

Mr. BEDELL. Thank you, Mr. Ransohoff.

Ms. Hecht.

STATEMENT OF MARJORIE MAZEL HECHT, FUSION ENERGY FOUNDATION, WASHINGTON DC

Ms. HECHT. Gentlemen, I am Marjorie Hecht from the Fusion Energy Foundation which is a nonprofit scientific and educational group with about 20,000 members nationally.

As our name implies, we promote fusion and nuclear energy technologies, in general.

I am very pleased to testify on behalf of this food irradiation legislation.

We would like to recommend the addition of two further points.

First, as I will describe later, electron beam irradiation, which is a spinoff of the beam defense program at Lawrence Livermore National Laboratory, is ready for immediate development.

Its promotion should be included in the work of the proposed Joint Operating Commission as well as a program of incentives for the private development of electron beam irradiation.

This, of course, would immediately obviate many of the objections we heard here today to the use of nuclear sources, although I am certainly speaking for the use of nuclear sources, also.

Second, we would suggest as a specific goal of the Joint Operating Commission an aggressive outreach program to transfer this technology as rapidly as possible to those countries in the developing sector that are in desperate need of ways to increase the quantity and quality of their food supplies.

I know many of these countries are interested. They have approached us for more information on this technology.

Now, I would like to talk also a little bit about the question of risk, but I am looking at risk totally from the other side.

I look at the risk of not going nuclear. What is the risk of our not pursuing food irradiation technology and advanced technologies in general, because I think that very often the consequences of some of the ideas we have heard here today and the opinions we have heard today are not thought out to their end point, which is the death of millions of people in the developing sector who need food, who need industry, and who are simply perishing.

So, today in this country, about 25 percent of our foodstuffs are lost to spoilage, and an estimated 50 to 60 percent in some of the developing countries of food that we ship there, of food that is produced there, never reaches its intended consumer because of insect infestation and spoilage.

In terms of grain alone, the amount lost yearly to insects, rats, et cetera, is 33 million tons of grain. This is enough to feed the entire U.S. population for 1 year.

Seventeen million tons of grain alone would mean the difference between life and death in Africa today. That is why we estimated it was an emergency program to begin to stop the deaths from starvation there.

So, this 33 million tons that is now going to waste is enough for 2 years to stop starvation and to stop millions of people literally from dying.

It is not just human consumption that can benefit from the increase in grain as a result of food irradiation.

If we are to adequately feed the world's population, we need to increase the amount of quality protein available, and this means that we need to triple the current amount of feed grains for animals which is now about 750 million metric tons.

The importance of providing a quality diet throughout the world cannot be overemphasized. It is not simply a third world problem.

The result of starvation conditions in Africa is that the continent today is engulfed in an AIDS epidemic that has already reached the United States and will begin to devastate this country, especially in urban and rural poor areas where the diets and living conditions are insufficient.

AIDS—in fact, Africa now is like a laboratory for AIDS, because people are so malnourished, conditions have deteriorated so much, and one of the first ways that you stop this process is by increasing the level of the diet.

We have to do this using all our advanced technologies from genetically engineering bacteria that will prevent frost damage—which has been in the news lately—to food irradiation to increasing the protein content of grain.

Now, I have summarized in my written testimony some of the reasons that we are supporting this food irradiation technology, and I think the previous panel dealt with many of the safety questions and other things.

What I would like to talk about is some of the objections raised by the environmentalists. We have studied the extensive research on food irradiation over the past three decades, and we have concluded unequivocally that the objections raised by the environmentalist lobby are capricious and without substance.

Some of these objections are perhaps raised in good faith by people who don't know the answers. Others are definitely raised by people who know that they are lying and misleading the public with their antinuclear propaganda.

There were a couple of examples—I won't go into detail—but one person who testified mentioned this material increase of cancer. Well, that is not true.

The rate of cancer cases has not increased. Cancer is a disease of the aging. Our society is getting older. People are living longer; therefore, you see more cancer. And if you control for the question of age, and you control for the people who smoke, why is the only exception to this?

There is no increase in the rate of cancer. That is one of the big environmentalist myths. There are others in terms of the nuclear power industry that I could also go into.

What we are seeing is an extension of the nasty process that has beaten back civilian nuclear energy in the United States using fear as its weapon.

The environmentalist lobby is trying to convince the population that advanced technologies are dangerous in general, that radiation must be especially dangerous because one can't see it, and that people are promoting new technologies because these people are evil and out only to make money for their industry.

Mr. BEDELL. Excuse me. What is your time situation?

Ms. HECHT. I would say about 2 minutes.

Mr. BEDELL. I will give you that.

Ms. HECHT. To these environmentalists, the scientific facts do not matter. I will give you one quote from the energy project director from Ralph Nader's antinuclear group, Critical Mass.

This person said:

> We haven't had time yet to fully research the issue of irradiated food, but I have an instinctive negative reaction. We oppose on principle the commercialization of nuclear material—whether it is Three Mile Island or smoke detectors, and I basically see this as a way of further legitimizing the weapons business.

Well, if there is any plot involved here, it seems to me it is that of the environmentalist lobby in its explicit Malthusian outlook which poses a real threat to the economy and the survival of our Nation.

These well funded and self-appointed advocates of the people readily admit that they think the world is overpopulated, that there are too many people, and that a smaller world would be beautiful.

Therefore, it is possible that such people have no qualms about killing off millions of people by restricting the spread of technology. Opposition to food irradiation—which could potentially provide more food quickly to people who are now starving—is just one example of the environmentalist behavior that directly leads to murder.

In a 1982 study that we did at the Fusion Energy Foundation, we calculated that 115 million people had died unnecessarily, mostly in the developing sector, as a result of the United States slowing down the goals of the Atoms for Peace Program and not spreading nuclear technology fast enough.

The point is that the introduction of nuclear power, an advanced technology, enables the economy to grow at a faster rate, and this increase in the growth rate provides for the increased health and well-being of the population.

If those 200 nuclear powerplants scheduled to be built between 1965 and 1980 had been built, the cheaper cost of nuclear energy and its large impact on the growth of productivity could have powered an additional 3 percent growth rate per year.

We haven't specifically modeled food irradiation, but the principle is the same. You get increasing productivity and you measure the result in human lives being saved, more people being able to live better lives.

Now, in terms of the developing sector market, I think that the delay in commercializing food irradiation here has greatly affected the rate of the spread of the technology abroad.

There are 28 countries now that have some food irradiation in process, but once we begin to implement the technology, there will be a tremendous boom in the developing sector, in particular.

Several countries in the past 3 years have approached us. In fact, I am meeting with one country tomorrow on how they can use food irradiation to increase the fish protein for their nation since they have abundant fish.

Well, I wanted to say a little bit more about electrobeam food irradiation which is, I think—could be called the second generation

food irradiation technology, the first generation being cobalt and cesium.

Ironically, we have delayed so long in developing the first generation technology that the second generation is now ready for commercialization.

I am talking about the induction linear accelerator developed as a spinoff of the Beam Defense Program at Lawrence Livermore National Laboratory in California.

This is a small accelerator. It can sit on the top of a large desk. It has the potential for providing a mass-produced, cheap, mobile, and efficient source of food processing using electron beams or x rays created by these electronic beams.

The benefits are tremendous. It fits on a 48-foot-long truck, for instance. It would cost about $1 million. As you can, I think, easily imagine, the ability to have something on a truck that could be transported in poor countries, especially, and go from crop to crop could really increase the use of this technology immediately.

I think one thing that hasn't been mentioned is the first generation technology using radionuclide sources would soon prove insufficient.

If we really had a crash program or even a semicrash program to develop the technology, we would soon find out that we didn't have enough cobalt and cesium as radiation sources.

I think the Livermore calculations on this was that if all the cesium and cobalt available in the world were used to irradiate food, we would be able to process only 6 ounces per person in the United States which is hardly enough for a crash program.

That is 6 ounces per day. The legislation before this committee presents an opportunity to begin to restore science and technology to its proper role as a driver for growth in our economy.

An aggressive policy to develop food irradiation will revolutionize food processing, will put more and better food on American tables more cheaply.

We will no longer feed 25 percent of our foodstuffs to promote the growth of insects, bacteria, and fungus.

Equally important, we can export this technology to countries where it is desperately needed and wanted, whose leaders understand that advanced technologies mean more of their peoples' lives will be saved from disease and starvation so they can be productive citizens.

Let there be no mistake, these developing nations understand fully that environmentalist demands can be measured in the number of deaths these demands will cause.

The developing nations do not want to import, quote, "western environmentalism." They want to import advanced technology.

By implementing the proposed food irradiation legislation, we can help ensure that science, not superstition and fear, becomes the basis for decisionmaking on economic policy and that advanced technology begins to turn around the U.S economic decline.

I also want to say in my testimony—I am on the question of labeling—that I don't object to using a label, but I think since there is no residue left in the food that it really is not completely necessary.

I think that American consumers can be educated that if they know that there are no bacteria in their food, if they know the food is clean, they will buy it.

If this joint commission can actually begin promoting the technology so people know what it is, I think American consumers will buy this food.

One of the things that I would wonder is whether we would then require natural foods to be labeled as processed with animal dung or protein content increased by insect eggs.

I really find that some of their objections are quite capricious, and I would suggest that we also begin labeling natural foods as to their true content; peanuts high in aflotoxin, for example, since natural peanuts are really a menace.

So, I thank you for this opportunity to testify.

[The prepared statement of Ms. Hecht appears at the conclusion of the hearing.]

Mr. BEDELL. Thank you.

Mr. Morrison.

Mr. MORRISON. Thank you, Mr. Chairman.

That is to both of you.

Mr. Ransohoff, some earlier witnesses seemed to indicate that your irradiation industry just ran rampant across the countryside proliferating and doing all those nasty things that come with the nuclear era.

You certainly are regulated in some way. I visited your facilities, and there is no question that someone was watching somewhere and that you have done a very good job with your responsibility.

Mr. RANSOHOFF. Thank you.

Mr. MORRISON. Can you speak to the level of regulation? You did comment that the industry was by and large safe and it probably would get better.

Mr. RANSOHOFF. We are heavily regulated, and of course most of us feel that we are too heavily regulated, but I think that in terms of the relative hazards I think in the last 10 years we have found that the regulatory—whether we are too heavily regulated or not, the other industries that had previously been considered less hazardous may have become more heavily regulated.

We are getting to be a very heavily regulated society. I think the methods of regulation could be improved. I think it would be healthy if it were less adversarial, and it would be healthier if it were more cooperative. There is no inherent lack of a community of interest between the regulators and the people operating companies such as ours. We are as interested in good safety practices as far as our employees and our community are concerned, as the regulators are, so I think that we are very heavily regulated.

We are fairly effectively regulated I think.

As far as proliferation is concerned, of course, I think that is a good thing. We would like to see more plants in more places. I do feel that that may not hold true for sources in a dispersal form. I think that that is a very serious problem, and I would like to get to that at another time with you, but by and large the industry has had a very good safety record, and it is a hazardous business. We do work with hazardous materials. We know it, and in our particular case, of course, we are not only dealing with ionizing radiation.

We are also dealing with chemicals, as we have it both ways, but we have had a good safety record so far, and I think in general while there have been some exceptions, the industry has done a pretty good job.

Mr. Mosimann. Would you take just 1 minute, Mr. Rosenhoff, and comment on the future supplies of cobalt. Do we have the capabilities as a nation to produce what we need? Mr. Hecht made comments about the lack of source material, and I am aware of your concerns about uranium and the fact that we are not going to produce any more, just for financial purposes, under Government ownership.

Mr. Rosenhoff. Again I would like to deal with this in closed session, because it does involve some proprietary information of ours. But we have been in the business of producing cobalt-60 for 20 years. The problem of the industry has been one of surplus, not one of shortage, until just a few years ago.

In the summer of 1981, Ontario Hydro had an accident with one of their power reactors, which reduced the production of cobalt-60 by 6 million curies a year, and that decrease in production created a shortage for 2 years. That period of shortage is now ended, and I think we are returning to the problem of glut, and that is a very serious problem so far as we are concerned.

I might point out that 6 ounces of food products per day per person in this country is close to 100 million pounds a day, which is a lot of food to process, and right now we don't see any viable markets for that, so I think it is a little premature to be worrying about a shortage of radioactive material.

Mr. Mosimann. So the Canadians can hold on up, but at $1.35 a curie behind us or will the price continue to be in that range?

Mr. Rosenhoff. I think $1.35 a curie is a fairly rare event. We haven't sold much cobalt at $1.35 a curie, small quantities to specialty users. I think you might get that price, and for cancer therapy applications it is more expensive because you have a very high maintenance requirement and much higher shipping costs, simply because the number of curies you are shipping is much smaller, but I think cobalt-60 in the range of $1 to $1.20 a curie is probably here to stay for quite a while.

We are getting some issues about increases in uranium costs from Canada, and the price could go somewhat higher, but I think there are a lot of ways of producing cobalt-60. There is a huge capacity for producing cobalt-60 as a byproduct of power reactor operations, and there are a number of surprises coming down the road as far as supplies of radio isotopes are concerned, so that I think that the concern about the shortage, while it was real for the past year or so, has generally been overstated, and I think that we will soon again be back into an era of gracious sufficiency, which is the situation that we found ourselves in for most of our experience here, and it is one of the reasons that we have put more emphasis recently on use than on production, simply because the market can become very oversupplied.

Mr. Mosimann. Thank you very much. Thank you, Mr. Chairman.

Mr. Dennis. Thank you. I need to understand about cobalt-60. Is that something that is produced from nonradioactive material?

Mr. RANSCHOFF. Right. Natural cobalt is cobalt-59.

Mr. BENNELL. Yes.

Mr. RANSCHOFF. We take natural cobalt, encapsulate it in stainless steel. When it is so encapsulated, it becomes a target. That target is placed in a nuclear powerplant where it absorbs neutrons. It is not a natural byproduct. It is a deliberate byproduct. After it has been irradiated for 1 year or 2 or 3 or 4, depending on the reactor, it then has a cobalt-60 content, usually in the range of 5 to 10 percent. That makes it active enough so that it can be economically used.

The irradiated target is then shipped to an encapsulation facility, in our case it comes to Dickerson, where the irradiated target is placed inside a clean stainless steel capsule, and at that point it is ready to use. There are very high standards of encapsulation. There have been very, very few source failures, even though many sources have been physically abused, and the sources are shipped all over the world.

Mr. BENNELL. One of the concerns that has been indicated is the problem with the radioactive wastes, so in moving into this area then, are we creating, first of all, radioactive material, and second, are we creating a radioactive waste about which we are going to have to concern ourselves with disposing?

Mr. RANSCHOFF. It is factual. I think that the level of concern, the level of appropriate concern, is grossly overstated.

First of all, cobalt-60 only has a half life of about 5 years, so that over a period of a lifetime, for example, of a person's lifetime, the activity degrades to one that is insignificant.

I think a lot of the emotional concern on radioactive wastes is concern over isotopes with very long half lives, where they will be around for thousands of years. Cobalt being a relatively inert metal, being encapsulated in stainless steel, I think is fairly easy to manage and store. You are dealing with very small physical quantities of material.

The second fact with regard to cobalt-60——

Mr. BENNELL. What is the amount of material you are talking about for a facility to irradiate pork, for example?

Mr. RANSCHOFF. Well, an irradiator that might have 2 or 3 million curies, for example, at a specific activity of 100 curies per gram would contain 25 kilograms of cobalt-60, 25 kilograms of cobalt, and the useful life of a cobalt-60 source is about 15 or 20 years.

At the end of that period, you will recall when I started this, I said that only 5 to 10 percent of the cobalt-59 atoms are converted to cobalt-60. To the extent that waste is really a problem, you could actually reradiate those targets, convert another 5 or 10 percent of the atoms from cobalt-59 to cobalt-60 and go through the process all over again.

For the most part, the cost of waste management or disposal is not sufficient to make it generally worth the trouble from a quality assurance standpoint and a reencapsulation standpoint and from the standpoint of shipping spent sources. It hasn't been generally worth the trouble to reradiate those sources.

I think that with the new prices for waste disposal, that is likely to change, so that all you really have to do to cause people like us

to recycle cobalt another time or two or three times is just to raise the price of disposal.

As a practical matter, we have been in business for 20 years, we could store all of the spent cobalt-60 sources we have produced in a very small space in the corner of our pool.

We haven't had to do that because most of those sources are still in use, but the volumes of material are very small. The material is inert, relatively inert. It is easily encapsulated and easily handled, and I don't really think that that is a subject of major concern.

Mr. BEDELL. You indicated, if I might proceed for another couple of minutes, you indicated some concern over cesium—is that a liquid or what is it?

Mr. RANSOHOFF. Cesium is an alkali earth, and it is probably the most active, I think it is the most active element in the periodic table.

It is difficult to put into an inert form. It can be done, but it is expensive.

Cesium that is separated from weapons waste has been put in its form of cesium chloride, which is a simple thing do to. It was a convenient form for waste storage, for encapsulation for storage, but cesium chloride is a very soluable salt, soluable to the extent of, putting it in curies, 70,000 curies per liter, which is a lot of stuff, and more significantly, cesium is monovalent. It decays into barium—am I getting ahead of you here?

As a result, as cesium decays, you create a deficiency so you are actually producing either cesium or barium metal. I have had a sort of running brouhaha with the Department of Energy on this subject for several years now, and there is a fairly serious disagreement between us on the wisdom—this is an unfair word, but I can't think of a better one—the wisdom of deploying cesium capsules.

When I have responded to public interest groups about radiation processing or about cobalt-60, there is always some genuinely interested person who asks the question: I understand what you say about the safety of these sources and I understand what you say about the integrity of the capsule, but what happens if a capsule fails?

The truthful answer to that question is, not much, because cobalt is so corrosion resistant, and if it is in a massive form, you are dealing with something that is easy to manage.

You are going to have some contamination of the facility. You are going to have a nuisance. You are going to have an inconvenience, but you are not going to have anything that could approach a public problem.

You simply can't say that about cesium chloride, and although the waste disposal capsules are rugged, they have a very heavy wall, they are massive.

You simply can't say anything very comforting in answer to the question, what happens if one of these sources fails? The true answer to that question is, you have a very, very serious mess on your hands.

Mr. BEDELL. Is that what happened at the one facility that they have talked about where there was some contamination of water supply?

Mr. RANSOHOFF. That was cobalt.

Mr. BEDELL. That was cobalt?

Mr. RANSOHOFF. That was cobalt in pellet form.

What happened there—I don't know what the details of the accident were, but they physically damaged the source and broke it. The pellets came out of the source, and were on the bottom of a pool.

The pool water was not well maintained, and they got a fair amount of corrosion of cobalt over the years, surprisingly little as far as I am concerned. The background of that was such that I think they were very lucky.

Mr. BEDELL. They dumped the water then or something?

Mr. RANSOHOFF. They had contaminated water, and they contracted with a party to clean it up that apparently spread the water around, so they had contaminated water seeping into the concrete and things like that, and it was a grand mess.

It did not, at no point did that become a serious public problem, but in the context—once that company eventually went out of business, and then had to deal with the problem of how do you decontaminate a facility that has been contaminated.

From the standpoint of returning that facility, that property, to a pristine condition, they had a pretty serious mess on their hands.

From the standpoint of public exposure, I would say the number of curies of cobalt-60 that were absorbed with the contamination was only a few curies, so that while it was a mess and a nuisance, and a costly one, it never became a matter of legitimate public concern, and, in fact, I don't think it was a matter of public concern in the area.

Mr. BEDELL. Ms. Hecht, you indicated that electron beam technology is really upon us.

Ms. HECHT. Yes.

Mr. BEDELL. I would have two or three questions.

First of all, with that technology, do you still have a problem of contamination of the facility, and so on?

Ms. HECHT. No; you don't. You don't have a nuclear source with it. You are using an electron accelerator which you turn off when you are not using it to irradiate food. In other words, with the cobalt source, when the machine isn't on, you are not irradiating food. It sits in a pool to protect it, but the electron beam accelerator is turned on and off like a light.

Mr. BEDELL. Economically, do you know how costs compare?

Ms. HECHT. Well, looking at the figures from Lawrence Livermoor, and it is much cheaper certainly than any chemical fumigation. They were looking at the raisin crop and the almond crop in particular. But it also is cheaper than using nuclear sources.

Mr. BEDELL. Have you looked into this, Mr. Ransohoff?

Mr. RANSOHOFF. No; but I am interested in where we can get one of these accelerators for $1 million and how reliable it is. We have no ethical or moral commitment to use radioisotopes instead of accelerators, any time we think that accelerators make more sense.

Mr. BEDELL. A radioisotope facility would be more than $1 million, wouldn't it?

Mr. RANSOHOFF. It would depend. The cost of radioisotopes for an irradiator to process the entire Hawaiian papaya crop would be on the order of $50,000 to $75,000 for a well-designed system, so that

the costs of radiation in most of these applications where you have—most of the applications—you can divide the applications into two groups, really.

Spices are a relatively low dose, but they use some significant cobalt-60. The applications are very, very low dose. And the principal cost in any facility to process irradiated products is going to be in handling equipment and things like that.

You are dealing with radiation costs that are in the tiny fraction of 1 cent per pound, so that most of the food applications that have been cleared or that are up for clearance are very low-dose applications. And the costs of radiation source is minor compared to the other costs of a facility.

In the case of medical supplies where your exposures are on the order of a megarad or more, the cost of radiation is a more significant factor. And there, Bectin-Dickinson has built an accelerator, has put in an accelerator to process medical supplies. They had a terrible time getting it started up, but it is my understanding that that facility is now operational.

I think that if you are really interested in the comparative economics of cobalt-60 and accelerators, it would be worth talking to them.

Mr. BEDELL. Who is that now?

Mr. RANSOHOFF. Bectin-Dickinson. They have got a commercial accelerator installed up in Canaan, CT.

Ms. HECHT. May I make a comment?

Mr. BEDELL. Yes.

I think our staff should check with them.

Ms. HECHT. The accelerator developed at the Livermoor Laboratory works on a slightly different principle, which is why it came out of the beam defense program. In other words, it is a new type of accelerator. It is not the same as the accelerators that have been used for the past several years in food irradiation, and that explains, I think, why it is cheaper, easier to use, and smaller.

I have papers with me that I would be happy to submit, if you like, to describe this. And I have pictures of it. They have one demonstration.

Mr. RANSOHOFF. I would be glad to be enlightened.

Mr. BEDELL. I think we would be interested in having that information, if you could.

Do you have any further questions, Mr. Morrison?

You indicated you would like to appear before us in closed session.

Mr. RANSOHOFF. Yes; I think there is a bit of a fallacy on the source materials situation, and we have been contending with this problem for a long time and have developed an approach to it that is different, that we think solves the problem of surplus and shortage, which we have experienced off and on for the past 20 years. It is the subject of patent applications that are either pending or in preparation. And I really don't want to be in a position of making a public disclosure.

I think I can say that the concern about radiation processing source shortage and the alleged need to distribute cesium sources, I think, is not well founded, and I would be willing to share it with

you. But I really can't do so under circumstances where it is a public disclosure.

Mr. BEDELL. The problem is that any time you talk to anybody in Government, as the President would tell you, it is not necessarily a private conversation. And I think some of us would be willing to meet with you, but you would have to be aware of the fact that no matter who you talk to, you can't be positive that that information will not somehow get out. And I don't think the members of the committee would want to be responsible for taking any proprietary information, in view of the fact that if it ever did get out, you might feel that the committee was responsible.

I am only speaking for myself. Do I understand that you can say this publicly; that you believe that there is no big shortage of material problem, but that you do have some concern over cesium because of the fact that you think it is somewhat more dangerous in terms of contamination than cobalt-60?

Mr. RANSOHOFF. Yes.

Mr. BEDELL. Can you say those things publicly?

Mr. RANSOHOFF. I think I can say publicly and authoritatively that there is no fundamental reason to be concerned about a long-term shortage of radiation processing sources, No. 1; and No. 2, that I think that the use of the Hanford capsules in their present form is not good public policy.

Mr. BEDELL. I think that takes care of our concerns. Thank you very much for your testimony.

Mr. RANSOHOFF. Thank you.

Mr. BEDELL. We appreciate your being here.

Mr. MORRISON. Mr. Chairman, since this is the last panel, I just want to take a moment to thank you and the staff for putting together this hearing. We, obviously, have heard both sides of the issue, and it is a perplexing one. I don't envy the Food and Drug Administration because the initial decision is theirs. I think this is a process that is going to go ahead, and let's make sure that it is done right.

[Whereupon, at 4:25 p.m., the subcommittee adjourned, subject to the call of the Chair.]

[Material submitted for inclusion in the record follows:]

STATEMENT BY:

DR. DONALD L. HOUSTON, ADMINISTRATOR
FOOD SAFETY & INSPECTION SERVICE

ON BEHALF OF:

UNITED STATES DEPARTMENT OF AGRICULTURE

AGRICULTURAL RESEARCH SERVICE (ARS)
ANIMAL & PLANT HEALTH INSPECTION SERVICE (APHIS)
FOOD SAFETY & INSPECTION SERVICE (FSIS)

BEFORE:

U.S. HOUSE OF REPRESENTATIVES
COMMITTEE ON AGRICULTURE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH,
AND FOREIGN AGRICULTURE

NOVEMBER 18, 1985

Mr. Chairman. Thank you for the opportunity to testify on House bill 696, which provides for "Federal coordination for the continued development and commercialization of food irradiation through the establishment of a Joint Operating Commission for Food Irradiation in the Department of Agriculture and through other means." Today I want to present the position of the Department of Agriculture (USDA) on H.R. 696. Then I will broaden the discussion by presenting the history of USDA research in food irradiation and USDA planning for the possible implementation of low-dose irradiation of fruits. My remarks will end with a discussion of our plans for implementing inspection at plants that irradiate fresh pork. First, H.R. 696.

USDA supports enactment of H.R. 696, provided sections 3, 4, and 6 are amended in the ways I will describe. Section 3 of H.R. 696 amends the food additive provisions of section 409 of the Federal Food, Drug, and Cosmetic Act (FDCA) to incorporate food irradiation processes. In effect, this amendment changes the legal definition of irradiation from a food additive to a process. Under the Federal Meat Inspection Act (FMIA), the Poultry Products Inspection Act (PPIA), and the Egg Products Inspection Act (EPIA), the Secretary of Agriculture now has independent authority to prohibit the use of a food additive, including irradiation, on a meat, poultry, or egg product, even if the food additive has been determined to be safe under section 409 of the FDCA. In most cases, the Secretary would follow the studies and findings of the Food and Drug Administration that the food additive is safe. In a few instances, however, the Secretary might consider it neccessary to conduct an independent review of the additive as applied to meat, poultry, or egg products--for example, if the Secretary believed that FDA findings did not adequately address the impact of the additive on these products. If the review found that the additive was unsafe or would be an adulterant when used in meat and poultry products, the Secretary could prohibit its use.

Because H.R. 696 would amend the FDCA to change the definition of irradiation from an additive to a process, the FMIA, PPIA, and EPIA should also be amended to continue the Secretary of Agriculture's existing authority to prohibit the use of irradiation on meat, poultry, or egg products if the Secretary deems it necessary, even if the food irradiation process has been determined to be safe under section 409. Our staff has drafted amendments to section 3 of H.R. 696 that would accomplish this objective; I will submit the suggested amendments to the committee.

Section 4 of H.R. 696 addresses the need for national uniformity in the regulation of irradition processing, labeling and marketing by prohibiting states and their political subdivisions from imposing requirements that are in addition to or different from those applied by or under the FDCA and the Fair Packaging and Labeling Act (FPLA). Meat and poultry products are exempt from the provisions of the FDCA to the extent they are regulated under the FMIA and PPIA, and they are excluded from the FPLA.

As a housekeeping measure, section 4 should be changed to ensure that states or their political subdivisions may also not impose requirements in addition to or different from those imposed under the FMIA, PPIA and EPIA. This recommended change would reinforce and make consistent the Department's current authority under the FMIA, PPIA and EPIA regarding pre-emption of federal requirements by state and local jurisdictions. For example, under Section 408 of the FMIA, no state may impose any inspection, marking, labeling, packaging or ingredient requirements which are in addition to or different than those made under the Act. It should be noted, however, that current pre-emption authority does not extend to the marketing of products as provided for in the bill. If the intent

of this section is to interfere with state and local regulation of intrastate marketing of irradiated products, we would have serious objections to its inclusion as inappropriate and perhaps unconstitutional.

Section 6 of H.R. 696 provides for the establishment within USDA of a Joint Operating Commission for Food Irradiation, composed of eight representatives of Federal agencies and the general public, to coordinate and review all research, development, and demonstration activities. USDA opposes enactment of section 6 because the proposed activities are already being carried out by Federal agencies, and the establishment of a commission will add a new layer of authority to Federal management of irradiation technology that could slow implementation of scientific developments.

In the past, coordination of research activities and exchange of information on the commercial implementation of irradiation techno~~logy~~ have been done by an interagency working group on irradiation. The Office of Science and Technology Policy is considering the formation of a subcommittee on food irradiation under the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC), which has broader representation of executive branch agencies than the proposed commission. In light of the policy-directing authority of CIRRPC, a Joint Operating Commission for Food Irradiation is not necessary.

The legislation would empower the proposed commission to collect and consolidate data produced by Federal agencies on food irradiation--a service now being provided by the National Technical Information Service of the Department of Commerce and the National Agricultural Library. Information developed by USDA is also disseminated to private industry and others through published papers, presentations at meetings and seminars, personal contacts, and activities of USDA's Extension Service.

A function of the proposed commission would be to educate the public about food irradiation. We agree that public education on the safety of food irradiation is an integral part of the commercial marketing of food. Once the capacity for irradiating large amounts of products is in place, USDA, through the Extension Service and other agencies, can provide information on the subject to consumers. Industry has already established the Coalition for Food Irradiation to educate consumers and to open public dialogue on the subject. We believe that the food processing industry, using the information developed by research programs and reviews by regulatory agencies, should have primary responsibility for consumer education.

Research Activities

USDA has conducted research on food irradiation for more than 30 years. That research has involved the use of low-dose irradiation of up to 100 kilorads as a quarantine treatment for insects in place of chemical fumigants and for the control of trichinae in pork; the use of medium doses of between 100 kilorads and 1 megarad for the control of micro-organisms for pasteurization; and the use of high doses above 1 megarad for sterilizing foods. I will now elaborate on USDA research programs in the low-, medium-, and high-dose irradiation of foods. Then I will turn to our plans for implementing low-dose irradiation programs for fresh fruits and fresh pork.

USDA Research on Low Dose Irradiation

As you know, Mr. Chairman, on February 14, 1984, the Food and Drug Administration (FDA) issued a proposed rule to permit the use of food irradiation at doses of up to 100 kilorads for inhibiting the growth and

maturation of fresh fruits and vegetables and for disinfesting foods of insects. The proposal would also permit the use of irradiation to disinfest spices of microbes at doses not to exceed 3 megarads, or 3,000 kilorads. We expect FDA to issue a final rule on the proposal soon.

For many years USDA has recognized the potential benefits of using low-dose radiation with cobalt 60 or cesium 137 as a quarantine treatment for fruits and vegetables. In 1964, we joined with the Atomic Energy Commission (AEC) to do the research needed to obtain a wholesome food additive tolerance for papaya. In 1973, we and the AEC submitted a petition supporting the FDA's position that the use of low-dose irradiation is safe.

With the loss of ethylene dibromide as a fumigant and the current lack of acceptable chemical alternatives, it is becoming more apparent that radiation treatment of certain commodities may play an increasingly important role in allowing their continued movement in national and international commerce. Accordingly, USDA's Agricultural Research Service (ARS) has expanded its research program in anticipation of an FDA ruling. ARS is concentrating on selected fruits and determining the radiation dosage necessary to provide quarantine security. Insect pests and commodities under investigation are the Caribbean fruit fly in mangoes, grapefruits, oranges, and tangerines from Florida; the Mexican fruit fly in mangoes, grapefruits, oranges, and tangerines from Texas; the West Indian fruit fly in mangoes from Mexico; the codling moth in apples and walnuts from Washington and California; and the cherry fruit fly in cherries from Washington. We expect to complete these projects by the fall of 1987. Results of the research can also be used to control pests on commodities from other areas, such as the Caribbean fruit fly in mangoes from Haiti and Puerto Rico, or the Mexican fruit fly in mangoes from Central America.

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Much of USDA's irradiation research has been with papayas. That work has shown that irradiation has definite advantages over chemical fumigation or vapor heat treatment of papayas because (1) it is much more efficient and can be a continuous process, (2) it ensures complete disinfestation, (3) unlike many fumigants, it leaves no residue on the fruit, (4) it prolongs the shelf life of fruit by delaying ripening, unlike fumigation and vapor heat treatment, which tend to accelerate ripening, and (5) in the long run it would produce a cleaner environment because a smaller volume of pesticides could be applied to the preharvested fruit crop if irradiation were used for quarantine treatment. Research on radiation treatment for the Mediterranean, Oriental, and melon fruit flies found in Hawaiian papaya was completed several years ago. We will begin studies of other commodities as soon as possible.

USDA Research in Medium-Dose and High-Dose Food Irradiation

Bacterial contamination of meat and meat products can be reduced at irradiation doses between 100 and 600 kilorads. Studies are under way to determine optimum exposure regimes for extending the shelf life of meat and poultry, reducing microbial spoilage, and reducing or eliminating food-poisoning bacteria. Research is also continuing on the effect of irradiation on structure, texture, and enzymatic activity within food products as well as changes in chemical composition at the molecular level. Use of irradiation may allow reduction of the amount of nitrite used for preserving meat.

Sterilization of food with high doses of irradiation has been investigated for many years by the Department of Army and USDA. In 1980, the Army transferred to USDA its programs related to the irradiation of meats, including data generated from completed work, funds to complete certain food toxicology studies already in progress, and specialized equipment.

The animal toxicology studies and summaries of information relating to the food chemistry, microbiology, and processing were completed. This data and the results of wholesomeness studies of precooked irradiated chicken were delivered to FDA on March 30, 1984. FDA indicated that it would review the data for its relevance to other proposed uses of irradiation in food preservation. Future USDA research will concentrate on low-dose irradiation studies for quarantine treatment, medium-dose studies for determining the relative susceptibility of bacteria to irradiation, and the effect of irradiation on food quality.

USDA Plans for Implementing Low-Dose Irradiation of Fruits

Thus far, USDA research suggests that irradiation could be successful as a commercial treatment to stop the spread of exotic pests. The Department believes that irradiation as a quarantine treatment has great potential for permitting the movement of several commodities in international and national commerce. Particularly attractive is its lack of potentially adverse effects on the environment. If low-dose irradiation is approved for use on fruits and vegetables, USDA will move as rapidly as possible to establish treatment schedules. USDA's Animal and Plant Health Inspection Service (APHIS) would establish treatment schedules based on ARS research.

There are several major considerations in establishing treatments for these commodities. Most important, the proper dosage level must be found that will kill pests while not damaging the fruit. For papayas, USDA has found that a dosage of 15 kilorads does not damage the fruit and is sufficient to give quarantine security protection against the three species of fruit flies that occur in Hawaii. This dosage is well below the 100-kilorad level that FDA has proposed as acceptable as a safe food additive tolerance.

[redacted] consideration to the construction of irradiation facilities. A cost [redacted] irradiation facility could be used as a fumigation facility. For instance, [redacted] of domestic crops, the facility should be located near packing facilities. For imported products, the facility could be in the United States or in the exporting country. Under our current procedures, USDA-APHIS approves the overseas facility. Further, an APHIS representative could be on site to supervise the treatment, maintain security of treated products, and verify that the products were treated at the prescribed dosage.

[redacted] of the proposal to move ahead quickly on the approval and use of low-dose irradiation on fruits and vegetables, an approval standard commonly used for assessing the safety and wholesomeness of irradiated foods is the dose limit that could [redacted] for the treatment of spices and spices, for cutting boards and of fruits for various kinds of fruit flies. In addition, before irradiation is used on a large commercial scale, industry needs to be convinced that the process can work. [redacted] in industry have already invested in developing irradiation treatment, demonstrations are needed to show each target pest for irradiation is feasible as a quarantine treatment.

As a final topic, Mr. Chairman, I will turn to the use of low-dose irradiation to control microbes in pork.

Low-Dose Irradiation of Pork

Research by ARS in cooperation with the Department of Energy has shown that radiation dose levels possible to kill trichinella. The pathogen is fatal only on ary it, [redacted] exposing the use of radiation to doses that is so low

killcards on pork co-ingers and fresh, non-heat-treated cuts of pork to control trichinae. USDA is continuing to evaluate the use of low-dose irradiation on meat to control other organisms of concern from a food-safety standpoint, such as toxoplasma.

USDA worked closely with FDA as that agency was developing its policy, and we fully support and concur in the decision to use irradiation technology as a means of combating the long-standing trichina problem. Although the risk of getting trichinosis is low, human trichinosis nevertheless remains a public health concern. The problem has cast a shadow over the pork industry for many years.

Trichinosis is a disease caused by the parasite Trichinella spiralis that forms microscopic cysts in the striated muscles of animals. Any warm-blooded animal can get trichinosis, but it is most likely to occur in certain carnivores, including bear, raccoons, bears, and rats. Generally, humans contract trichinosis by eating raw or undercooked meat, usually pork, containing trichinae cysts. The disease can be prevented by cooking meat properly to kill any trichinae that may be present. The irradiation of pork at doses of from 33 to 100 kilorads sterilizes trichinae so that it cannot reproduce in the human intestinal tract. Thus, no offspring will be produced to invade muscle tissue and cause trichinosis.

Current meat inspection regulations on trichinae control classify pork into two main groups: ready-to-eat pork products and fresh pork. Ready-to-eat products include cooked hams, dried-cured hams, cooked or cured sausages, and other sausages such as salami and pepperoni. Because consumers may not reheat

ready-to-eat pork products sufficiently, our regulations require that these products be treated by heating, freezing, or curing to kill trichinae. On the other hand, fresh pork products are not routinely treated for trichinae; instead, we rely on public information campaigns to educate consumers about the importance of cooking raw pork sufficiently to kill trichinae.

USDA considers FDA's July 22 approval of the irradiation of fresh pork as another approach that FSIS, as a public health agency, may take in dealing with the risk of human trichinosis. Shortly after FDA's action, USDA received a petition from Radiation Technology of Rockaway, New Jersey, requesting FSIS approve the use of irradiation for the treatment of fresh pork. On the basis of that petition, FSIS began:

(1) developing a final rule adding the irradiation of fresh pork to the list of food additives found in the federal meat inspection regulations (although the rule will be final when published, it will provide for a public comment period after publication);

(2) developing interim guidelines relating to plant operating procedures, the safety and training of employees, sanitation, facilities, quality control programs, and labeling; and

(3) preparing a proposed rule that will outline our specific regulatory authority and the direction we propose to take in developing long-term procedures and policy relating to the regulation of irradiation. I want to emphasize that the final rule which is developed as a result of this phase of rule making may modify the interim guidelines.

A workable irradiation inspection program should be in place shortly after the first of the year. Thus, industry will be able to take advantage of the new technology reasonably quickly and at the same time that we are going through rule-making proceedings. We have already conducted two in-depth training programs for FSIS personnel, including the inspectors and supervisors who would be responsible for the three plants in New Jersey, North Carolina, and Arkansas owned by Radiation Technology. The training was put together by consulting firms with experience in irradiation and was specifically designed to address problems that might occur in the irradiation of meat. We are continuing our training programs to implement the interim guidelines on which I would like to further elaborate.

Under the guidelines, every irradiation plant will have to submit a quality control program to FSIS for approval before it may irradiate pork. The program must describe fully how each plant intends to operate under differing conditions of product and packaging variabilities. Every variation may require a separate process control program if the variation affects the dose. Different products interact with irradiation differently, and we must have evidence that each type of product will receive a dose within the range approved by FDA. If the dose is under 30 kilorads or over 100 kilorads, the product would not be in compliance with our regulations.

USDA inspectors will monitor critical control points identified in quality control programs to verify that the irradiation process is being applied correctly. Examples of critical control points in irradiation processing are:

(1) the distance of the products from the irradiation source;

(2) the products' position in relation to the source; and

(3) the amount of time products are exposed to the irradiation source.

In addition, the strength of the radioactive source diminishes over time. Therefore, quality control programs will also have to account for this variation so that products always receive the correct dose.

In addition to FSIS requirements concerning facilities, equipment, and sanitation, irradiation facilities must comply with the requirements of certain other Federal agencies before a grant of inspection is issued. The use of radioisotopes in commercial irradiators is governed by either the U.S. Nuclear Regulatory Commission (NRC) or in Agreement States by their Radiation Control Offices. The regulations which define the basic licensing and other requirements for the protection of workers and the public and the handling and disposal of byproduct materials is contained in Title 10 of the Code of Federal Regulations or in the Agreement States NRC approved implementation of this code. They must also meet the requirements of the Occupational Safety and Health Administration concerning general worker safety and the Environmental Protection Agency concerning the disposal of wastes other than byproduct materials. USDA will work closely with these other Federal agencies.

Labeling of Irradiated Pork Products

Another important component of the interim guidelines will focus on wholesale and retail labeling of irradiated pork products. With regard to wholesale labeling, irradiated products in commercial distribution channels must be clearly labeled as irradiated. This labeling must be maintained at every stage

of distribution to prevent the possible re-irradiation of foods. For retail labeling, we will require that irradiated fresh products bear a label statement to that effect. Processed meat products, which are so-called "second-generation" foods, may contain various amounts of meat and other ingredients. Therefore, we are considering the need for processed products made from irradiated food to bear a label statement that the ingredient(s) have been irradiated. We are aware that there may be a level of irradiated ingredients that would be so insignificant as to not require labeling.

Conclusion

Mr. Chairman, we want to emphasize that the commercial irradiation of food will require more precise control of dosage than the irradiation of nonfood products. Irradiation for the sterilization of medical supplies or polymerization requires only that minimum exposure criteria be met. In contrast, food processing will require continuous monitoring to ensure that carefully defined limits of minimum and maximum exposure are maintained at all times. A maximum exposure dosage for food is needed to ensure regulatory compliance as well as to avoid damage that has been observed in some commodities, such as grapefruit. A minimum exposure level is needed to ensure that regulatory requirements, such as those for quarantine or trichinae control, are met.

Food irradiation has not been adopted as rapidly in the United States as in some other countries. In the United States, only spices are irradiated on a large-scale commercial basis. FDA approved irradiation treatment at 20-50 kilorads for insect disinfestation in wheat and wheat flour in the 1960's, but

it has not been implemented by the U.S. grain industry. The lack of implementation of the technology for wheat indicates that other industries may be slow to use irradiation, especially when cheaper alternatives may be available.

In addition to developing methodology for use by agricultural industries, USDA's proper role in the development of a new technology includes ensuring that all safeguards have been identified for consumer protection and product quality. USDA will continue its research efforts and will continue to develop regulatory programs and provide technical information on irradiation to industry and consumers.

This completes USDA's testimony, Mr. Chairman. My colleagues and I will be happy to answer any questions you or other Members may have.

(Attachment follows:)

Proposed Amendments to the Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act

1. The Federal Meat Inspection Act is amended -

(a) in section 1(m)(2)(A) (21 U.S.C. §601(m)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 1(m)(2)(C) (21 U.S.C. §601(m)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 1(m)(2)(D) (21 U.S.C. §601(m)(2)(D)) by inserting "food irradiation process," after "food additive,";

(d) in section 1(m)(7) (21 U.S.C. §601(m)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 1(r) (21 U.S.C. § 601(r)) by inserting "'food irradiation process'," after "food additive,'".

2. The Poultry Products Inspection Act is amended -

(a) in section 4(g)(2)(A) (21 U.S.C. § 453(g)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 4(g)(2)(C) (21 U.S.C. § 453(g)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 4(g)(2)D) (21 U.S.C. §453(g)(2)(D)) by inserting "food irradiation process," after "food additive,";

(d) in section 4(g)(7) (21 U.S.C. §453(g)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 4(y) (21 U.S.C. § 453(y)) by inserting "'food irradiation process'," after "'food additive',".

3. The Egg Products Inspection Act is amended -

(a) in section 4(a)(2)(A) (21 U.S.C. §1033(a)(2)(A)) by inserting "or a result of a food irradiation process" after "food additive";

(b) in section 4(a)(2)(C) (21 U.S.C. §1033(a)(2)(C)) by inserting "or has been treated by any food irradiation process" after "food additive";

(c) in the proviso of section 4(a)(2)(D) (21 U.S.C. §1033(a)(2)(D)) by inserting "or food irradiation process," after "food additive,";

(d) in section 4(a)(7) (21 U.S.C. 1033(a)(7)) by inserting immediately before the semicolon ":Provided, That an article which is not otherwise deemed adulterated under this clause shall nevertheless be deemed adulterated if the use of a food irradiation process, in or on such article, is prohibited by regulations of the Secretary";

(e) in section 4(u) (21 U.S.C. §1033(u)) by inserting "'food irradiation process'," after "'food additive',".

DRAFT

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

STATEMENT

BY

FRANK E. YOUNG, M.D., Ph.D.

COMMISSIONER

FOOD AND DRUG ADMINISTRATION

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,

RESEARCH, AND FOREIGN AGRICULTURE

COMMITTEE ON AGRICULTURE

U.S. HOUSE OF REPRESENTATIVES

NOVEMBER 18, 1985

FOR RELEASE ONLY UPON DELIVERY

Mr. Chairman:

I welcome this opportunity to discuss with the Subcommittee the activities of the Food and Drug Administration (FDA) in the area of food irradiation.

BACKGROUND

While the use of irradiation for preserving food was explored as early as 1936, food irradiation research in the United States started in earnest in the late 1940's. It was only a few years later, in the early 1950's, that the U.S. Government became interested in this new processing method. At that time the U.S. Army conducted a feasibility study of irradiated food and, based on organoleptic and biological tests, concluded that food irradiation could provide a wholesome, good-tasting, economical, and shelf-stable product for field rations; reduce dependence on refrigeration; and greatly reduce food handling costs for the military.

There was also substantial civilian interest in this new technology. As part of President Eisenhower's "Atoms for Peace" program, the Atomic Energy Commission (AEC) had an early interest in food irradiation, especially at low-doses for insect control and shelf-life extension of fruits and vegetables, as well as for control of microorganisms in food.

FDA's involvement in irradiated foods started in the early 1950's when, in close cooperation with the military, the U.S. Department of Agriculture and interested parties in the private sector, the Agency suggested wholesomeness testing for these products. In 1958, Congress passed the Food Additives Amendment to the Federal Food, Drug, and

Cosmetic Act. This amendment required that use of a source of radiation to treat food be shown safe and that authorizing regulations be issued before irradiated foods could move in interstate commerce.

EFFECTS OF FOOD IRRADIATION

Before discussing the regulatory action of FDA involving irradiated food, first let me briefly review the technical effects of food irradiation. (A table listing the technical effects of radiation on food is attached to my statement as Appendix A.) To a significant degree the technical effect of radiation on foods is dependent on three principal factors:

-- First, the effect of radiation is cumulative, and is directly proportional to the total dose of radiation absorbed by food.

-- Second, the effects of radiation on materials are dependent on the complexity of the material irradiated and the environmental conditions present during irradiation, such as the temperature, moisture content or oxygen content.

-- Third, the effects of radiation is a function of a type of radiation as characterized by its energy level.

For example, living material is affected more profoundly than inanimate material; multicell organisms are affected more readily than single cell organisms; growing organisms are affected more readily

than dormant organisms. Thus, irradiation can affect sprouting of root crops at low doses (5-15 krads). Similarly, you can delay the ripening of fruits and vegetables because they are still "alive" and maturing.

Insects are affected at about 15-100 krads depending on their stage of development (egg, larvae, adult). At doses above 100 krads, microorganisms are significantly affected.

Finally, the dose required to produce a commercially sterile product (i.e., the dose required to produce a one trillion-fold reduction in pathogenic microorganisms) is about 2-6 Mrad, depending on the food. It is important to note that even at these sterilizing doses, enzymes and viruses are relatively unaffected.

SAFETY ISSUES

The fundamental health concern for safety of foods treated with ionizing radiation is twofold:

-- First, there is concern for the possible long-term toxicological effects of the radiolytic products formed in foods as a consequence of this irradiation process. The degree of concern is proportional to the absorbed dose and the significance of the food in one's diet.

-- Second, there is concern about the effects of irradiation on the microbial flora of the food, and on the nutritional quality of the treated food.

There is also the basic premise that radiation must not make food radioactive. We now know that this does not happen if radiation sources are restricted to those of certain specified energies.

as have known since the 1950's that a major problem with safety evaluation of irradiated foods has been the difficulty in establishing the identity, amount, and toxicity of the radiolytic products formed in food by irradiation. In the beginning, attempts were made to assess these products for safety by using traditional animal feeding studies. This was thought to be the most pragmatic approach for establishing the safety of irradiated foods in the absence of more sensitive analytical methods. Because of these concerns, in the fall of 1970, we established the Bureau of Foods Irradiated Food Committee, consisting of six Agency scientists. The Committee was charged to review the Agency's practice for evaluating the safety of irradiated foods and to reassess criteria for safety evaluation according to the current state-of-the-art knowledge in toxicology, nutrition, and radiation chemistry. The basic objective of this study was to develop criteria for assessing irradiated foods that would more rationally establish safety than traditional animal tests and yet assure safety to the same degree that is expected for other foods in the American food supply. The Committee concluded that:

— existing data established the safety of foods irradiated below 1 kGy (100 krad) and of minor ingredients, such as spices, irradiated at higher levels,

— that the type and amount of radiolytic products formed in foods irradiated below 1 kGy were such that the irradiated food was as safe as the nonirradiated food, and

On March 27, 1981, the Agency published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register setting forth the criteria for safety evaluation recommended by the International Food Scientists. This was a key first step in the administrative process to establish the operating criteria for evaluating safety data for irradiated foods.

After a full analysis of all comments to this ANPR and following discussions with a wide variety of industry, university and international scientists, FDA, on February 26, 1986, proposed a rule in the Federal Register to permit the use of irradiation for (1) sprout inhibition and shelf-life extension of fresh fruits and vegetables, and for insect disinfestation of food at doses not to exceed 1 kGy (100 krad), and (2) for sterilization of spices at doses not to exceed 30 kGy (3 Megarad).

Except for spice sterilization, this proposal did not deal with the use of radiation for the control of microorganisms, such as bacteria, molds and yeast in foods, and it did not deal with parasite control in meats, such as trichina.

The proposal provided for a 60-day comment period which FDA extended for an additional 30 days in response to several requests. Over 1,000 comments, many of which raised substantial issues, were received.

In 1984 the Agency received a petition to amend the food additive regulations to permit gamma radiation treatment of pork to control Trichinella spiralis. A year later on July 22, 1985, we published in the Federal Register a final rule permitting this use. During the 30-day objections period, we received several requests for a hearing and a stay of this regulation. We are currently evaluating the requests.

In addition to the approval for pork irradiation, we have expanded the list of the spices and vegetable seasonings and have approved the use of irradiation to control insects and microbial contamination of dry enzyme preparations.

PUBLIC AWARENESS

Although many uses of irradiation have been demonstrated by science to be safe, the average consumer continues to confuse food irradiation with the problems and potential hazards associated with the use of irradiation for weaponry or for power generation. In fact, some have suggested that the public's misconception is so strong that a different term (such as "gaia wave energy") should be used to describe the low level energy radiation applicable to foods. Clearly greater public education is needed to inform consumers of all relevant facts about irradiation. Many people do not know, for example, that irradiation has been used for a number of years in the sterilization of food prepared in hospitals to feed patients with immune deficiency and for astronauts in the NASA program with no indication of any harmful effect. Many also do not understand that the irradiation process does not produce a radioactive product and, more importantly, that even in the use of isotopic sources of ionizing radiation, there is no generation of nuclear wastes.

We are pleased that industry has initiated a public education effort to demonstrate to the consumer that this is a safe and potentially valuable process. One has to be careful, however, that the process and its potential are not oversold. Food irradiation is a very useful technology but only one of several that are important if we are to maintain and, indeed, improve our food supply. We have been fortunate in the United States that we have not only been blessed with an abundance of food but with a technological base that has allowed us to continue to expand our food supply as our population has required.

ANALYSIS OF H.R. 696

In your letter of invitation you requested that we comment on H.R. 696, the "Federal Food Irradiation Development and Control Act of 1985." This legislation contains two principal sections relevant to this Agency. First, H.R. 696 removes a source of radiation from the definition of a food additive in section 201(s) of the Federal Food, Drug, and Cosmetic Act (the Act) but continues its regulation under the food additive section (section 409) of the Act by adding it back into this section as a "food irradiation process." Second, the bill establishes a Joint Operating Commission for Food Irradiation within the Department of Agriculture, and includes the Department of Health and Human Services (HHS) within the membership of this new Commission.

Definitional and Regulatory Changes

The Food Additives Amendment of 1958 specifically included a source of radiation in the definition of a food additive. The food additive section of the Act requires premarket approval before a source of

radiation may be used to process food, i.e., the source of radiation must be determined to be safe by the FDA before it can be used on a food to be introduced into the marketplace.

While we are uncertain as to the objective in H.R. 696 of reclassifying a source of radiation from a food additive to a "food irradiation process," we have no objection to the change because the Act as amended would appear to permit us to regulate a source of radiation in virtually the same way under the food additive premarket approval section of the Act.

Joint Operating Commission for Food Irradiation

H.R. 696 creates the Joint Operating Commission for Food Irradiation within the Department of Agriculture with HHS membership. We view the creation of such a Commission to coordinate intergovernmental irradiation activities to be unnecessary. Currently, FDA, the Department of Agriculture, the Department of Commerce's National Bureau of Standards, the Nuclear Regulatory Commission and other Federal agencies cooperate to resolve mutual concerns and coordinate activities in this area; this procedure has worked well and we see no need for a statutorily created body.

Furthermore, inclusion of HHS on the Joint Operating Commission could produce potential conflicts because under section 6(c)(7) of H.R. 696, the Commission would petition FDA under section 409 of the Act to approve expanded uses for the commercial application of food irradiation. FDA, however, regulates food additives under a delegation of authority from the Secretary of HHS. Consequently, inclusion of HHS

on the Commission would put the Department in the anomalous position of petitioning itself to approve new uses of food irradiation.

Summary of Position on H.R. 696

We have no objection to the reclassification of a source of radiation from that of a food additive to that of a "food irradiation process." However, we believe that it is crucial that the legislative history to accompany this legislation elaborate on remarks already made which indicate that the definitional and regulatory changes in H.R. 696 in no way are meant to affect the FDA's ability to continue to regulate under section 409 of the Act the safety of foods treated with radiation. In introductory remarks printed in the Congressional Record for January 24, 1985, Congressman Morrison, the bill's sponsor, said that, despite the change in definition so that food irradiation will be considered a "process," FDA will still retain its general authority to regulate food irradiation under the same premarket approval process as now exists.

We think that the Joint Operating Commission for Food Irradiation is redundant, causes conflict of interest problems for this Agency, and some of its functions could better, more effectively, and more appropriately be performed by the private sector. We urge you to reconsider the creation of this Commission in the legislation.

Finally, we have some technical concerns with the manner in which H.R. 696 amends the food additives section of the Act and would be pleased to work with relevant Congressional staff to resolve these difficulties. In addition, we have questions about the meaning and

intent of section 4 of the bill, which, among other things, would restrict the States from imposing additional or different requirements from those established by FDA relating to the irradiation processing of food, or to the labeling or marketing of irradiated foods. Our questions here focus on the meaning of the word "marketing," which is not defined in either the bill or the Federal Food, Drug, and Cosmetic Act.

CONCLUSION

FDA's role in food irradiation over the years has been to evaluate its safety and effectiveness for its intended uses. After some 40 years of investigation we have concluded that, at the levels which we have established in our proposals, the process is safe and effective. It is now, we believe, the turn of industry and the private sector to begin to utilize this technology and to proceed from what has been, up to now, a fundamentally small scale commercial activity, to its use as an important component of our food processing chain. We also believe that the industry will need to continue their public education effort to demonstrate to consumers that federally approved food irradiation is a safe and potentially valuable process. FDA will continue to fulfill its responsibility by evaluating the safety of the process, particularly if information is developed to justify use at levels higher than those which have been approved or proposed thus far.

This concludes my statement, Mr. Chairman. If you or your colleagues have any questions, we would be glad to respond to them.

(Attachments follow:)

APPENDIX A

TECHNICAL EFFECTS ON FOOD

A. Sterilization*	2,000 to 6,000 krads (2 to 6 Mrads)
B. Texture Modification	700 to 1,000 krads
C. Microbial Control (bacteria, fungi)	100 to 1,000 krads
D. Insect Control	Less than 100 krads
E. Maturation Inhibition	Less than 100 krads
F. Parasite Control	Less than 100 krads

NOTE: * Irradiation at practical doses will not affect viruses or enzymes.

Appendix B

IRRADIATED FOODS

History of Actions

- February 1963: FDA approved gamma radiation for the radiation preservation of canned bacon.
- August 1963: FDA anproved gamma radiation for control of insect infestation of wheat and wheat products.
- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.
- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.
- December 1964: FDA approved X-radiation for the radiation preservation of canned bacon.
- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.
- July 1966: FDA approved labeling requirements for food treated by radiation.
- October 1968: FDA rescinds the bacon regulations.
- September 10, 1979: Director, Bureau of Foods establishes the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.
- March 27, 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.
- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting these conditions.
- July 5, 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.
- Feburary 14, 1984: Proposed rule published in the Federal Register. FDA proposes a regulation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.
- June 19, 1984: FDA amended the food additive regulation to provide for the safe use of a source of gamma radiation to control insect infestation in garlic powder, onion powder, and dried spices.
- April 18, 1985. FDA expanded the specific list of dried spices and vegetable seasoning to include additional herbs, spices, and vegetable seasonings, and blends of these seasonings.
- June 10, 1985. FDA amended the food additive regulation to provide for the safe use of a source of gamma radiation to control insect and microbial infestation in certain dried enzyme preparations.
- July 22, 1985. FDA amended the food additive regulations to permit gamma radiation treatment of pork to control Trichinella spiralis.

ENVIRONMENTAL POLICY INSTITUTE

STATEMENT OF ROBERT ALVAREZ*

BEFORE

THE SUBCOMMITTEE ON DEPARTMENT
OPERATIONS, RESEARCH AND FOREIGN
AGRICULTURE OF THE HOUSE COMMITTEE
ON AGRICULTURE

REGARDING

H.R.696 - A BILL TO PROMOTE THE
COMMERCIALIZATION OF FOOD IRRADIATION

NOVEMBER 18, 1985

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SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

The Environmental Policy Institute (EPI) strongly opposes enactment of H.R. 696 - a bill to encourage the commercialization of food irradiation technologies. There are several compelling reasons for this.

First, the irradiation of food involves an ultrahazardous technology which poses several types of risks to the public and workers. Food irradiation facilities, as envisioned by the its proponents, will utilize very large quantities of intensely radioactive substances which, even in very small quantities can cause death from acute radiation syndrome. One food irradiation facility will be generating as much as 10 times more low-level radioactive wastes (in curie content) than all sources combined in the United States for the year 1981.

Food Irradiation facilities pose serious contamination risks to local water supplies due to the potential for leaking or ruptured capsules containing radioactive sources in cooling pools. Moreover, the regulations governing public exposures from irradiation facilities are much more lax than for commercial nuclear power plants. For example, citizens living near an irradiation facility are allowed to recieve 20 times more radiation exposure yearly (500 millirems) than from commercial reactors (25 millirems).

Second, irradiation facilities are poorly regulated. The Nuclear Regulatory Commission have allowed industrial radiation facilities to be located in populated areas which has led to serious public health consequences. For example, a food school kitchen serving 40,000 children was heavily contaminated by a commercial radiation plant in 1979

at levels in excess of EPA standards. A variety of accidents have occured with radioactive sources in the commercial sector. Sometimes radioactive sources are simply lost. At one facility, Radiation Technology, in New Jersey, company employees were caught by the Nuclear Regulatory Commission placing radioactive materials in a dumpster for disposal as non-radioactive garbage.

Third, the risks of occupational exposures in food irradiation facilities are considered by the NRC staff to be the most dangerous. This is because of the potential for exposure to lethal levels of radiation. In 1977, a worker at Radiation Technology Inc. was reported by the NRC to have recieved a dose of 222 rads (radiation absorbed dose) which is close to the dose which would be lethal to 50 percent of the people so exposed. It also may be the largest occupational exposure to ever occur at an NRC licensed facility. The incident was directly caused by a management decision to allow the source to be raised with inoperative interlock and safety devices, in violation of license requirements. That the NRC allowed this plant to continue operation -iven such a serious breach of safety is an example of the federal government' weak regulation of such a dangerous industry.

Occupational risks to workers chronically exposed to low-level radiation at the DOE's Hanford facility, which processes radiocesium for food irradiation are being found to be quite serious. Hanford workers have been shown in a series of studies to have risks of dying from radiation-induced cancer which are 10 to 20 times greater than current protection standards assume.

Fourth, irradiation intended to eliminate one food hazard may intensify another. From the environmental perspective, the creation of radiation resistant bacteria and viruses pose health risks which deserve further study before food irradiation is commercialized.

Fifth, the food irradiation industry is the sole creation of the nuclear weapons industry which is desperately seeking ways to externalize their enormous nuclear waste costs. Under a scheme offered by the Department of Energy (DOE), the DOE is proposing to lease its radioactivity then offer to transport the sources to and from facilities. After the source has been spent, but is still quite radioactive, the DOE plans to return the radioactive wastes back to the Hanford facility for disposal in shallow land fills. DOE is planning to do this through a major relaxation of their internal radioactive waste management standards. By creating an artificial demand for radioactivity, this will allow the DOE to have the option of pushing more radioactive wastes on to the rest of society.

Sixth, food irradiation is another nuclear boondoggle that will require multi-billion dollar subsidies from the taxpayer for a technology with no proven history of commercial success. If left to fend for itself in the marketplace, the food irradiation industry would have been dead by the late 1950's. The major subsidies by the nuclear weapons program over the years (which for the most part was decided in secrecy) has more to do with the viability of food irradiation, than it's commercial need.

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and replacement of a certain fraction of the radioactive source in order to maintain a uniform energy field due to radioactive decay.* Thus, one food irradiation facility of this size would be generating every five years about 1.5 million curies of low-level radioactive wastes -- or 10.5 times the total radioactive content of all generators of low-level radioactive wastes in the United States for the year 1981.

Tens of millions of curies of a substance which can cause death from acute radiation syndrome in quantities of a few curies are expected to be located in densely populated areas, near food growing areas and important watersheds. Trucks hauling similarly large amounts of this deadly substance are expected to pass through cities and towns with minimal regulation.

The effects of chronic exposure to low-levels of ionizing radiation to people living near or working in radiation industries are now being shown in studies to be at least ten times greater than current protection standards assume. Therefore, food irradiation facilities pose not only ultrahazardous risks from severe accidents, but also significant risks of latent disease and genetic harm from routine operations and lesser accidents.

An important concern is the potential for surface or groundwater contamination due to leaky or ruptured jackets which contain the radioactive source. Food irradiation facilities with large sources will depend on constant flowing water drawn from a local supply to cool the source in a pool. If the jacket of a source corrodes,

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Cesium -137 has a half-life of 30 years.

breaks down from metal fatigue, or is ruptured by outside events, the radioactive source will then leak into the pool and eventually into the outside water supply. This is a particularly serious concern for radiocesium, which has been put into a salt form by the DOE. Unlike radiocobalt which is in a metallic form, radiocesium is extremely water soluable.

INADEQUATE REGULATION OF IRRADIATION FACILITIES

The regulatory record relative to commercial uses of radiation has much to be desired. A variety of accidents have already occured with medical or research radioactive sources. Sometimes radioactive sources are simply lost. Radioactive sources have somehow leaked out of both processing plants and the hospitals or research facilities where they are used.

The best publicized processing leak occured at American Atomics in Tucson, Arizona, where an outraged Governor eventually had to send in the National Guard to dispose abandoned radioactive tritium in 1979. This total breakdown in regulation occured both at the state level, where Company Officials sat on the state regulatory board and the Nuclear Regulatory Commission (NRC) which simply did nothing, when it was apparent that this facility posed unnacceptable risks to the community.

The plant was located in a densely populated area which meant that frequently leaked tritium (a radioactive form of hydrogen or H_3) ended up in a public school food kitchen across the street contaminating food served to 40,000 children. In 1978 alone the plant admitted

leaking 284,000 curies of tritium gas into the atmosphere. After a summer of revelations about American Atomic's dumping radioactive liquids directly into the city sewer system, food in Tucson's food kitchens that measured 2.5 times above permissible levels, high radiation levels in plants and people living near the facility, ans swimming pools more radioactive than EPA's drinking water standards, the company surrenderd its license and abandoned the facility.

Proponents of food irradiation argue that "it can't happen here." They point out that their radioactive sources are contained in rods and cannot escape in gases or liquids like the tritium at American Atomics. As mentioned earlier, food irradiation facilities have the real potential for contaminating local water supplies due to leaking rods in cooling pools. Additionally, radioactive sources must be fashioned into forms for use in irradiation facilities. One company which handles cobalt-60 has already been embarrassed by the discovery of Cobalt-60 on the railroad tracks beside the Neutron Products plant in rural Dickerson, Maryland. Eventually, the company was made to alter its practices by the state, but only after citizens living in Dickerson organized after learning more about this facility's operating history. At another facility , Radiation Technology Inc. in New Jersey, the NRC was cited in court litigation that this facility was illegally placing radioactive materials in a dumpster for disposal as non-radioactive garbage.

WORKER SAFETY

Mr. Robert Alexander, Occupational Standards Branch Chief of the Nuclear Regulatory Commission's Office of Research considers occupational exposures at irradiation facilities to be the most dangerous in the radiation "byproduct " industry. This is because of the potential for total body exposure to levels of external radiation which can cause prompt death. Thus, it is extremely important that irradiation facilities have stringent safety practices. Unfortunately, this has not been the case.

In 1977, a worker at Radiation Technology in New Jersey accidentally opened the door to the radiation chamber when the source was exposed. He recieved an estimated dose of 222 rads (radiation absorbed dose) to his total body. This event may represent the largest occupational radiation exposure to ever occur at a facility licensed by the NRC. Moreover, this dose is almost large enough to kill 50 percent of the people so exposed (300 rads = LD_{50} dose). This dose is more than enough to double the risk of this person dying from a radiation induced cancer , according to the risk estimates of the NRC.

Occupational risks to workers processing radiocesium at the DOE's Hanford Plutonium Works in eastern Washington have been shown to be quite high. In a series of studies, performed by Dr. Thomas Mancuso and His colleagues Dr. Alice Stewart and George Kneale, workers who have been followed at Hanford for 36 years (1944-79) bear risks dying from radiation induced cancer which are 10 to 20 times greater than current protection standards assume. Moreover,

Energy Department contractors have found greater than expected risks of dying from cancer and non-cancers in eleven additional population of federal radiation workers.

POTENTIAL FOR CREATING RADIATION-RESISTANT ORGANISMS

Irradiation intended to eliminate one food hazard may intensify others. From the environmental perspective, the creation of radiation resistant bacteria and viruses poses health risks which deserve further study. Radiation resistant mutants of Salmonella have been developed by repeated irradiation under laboratory conditions, and radio-resistant strains are also found in environments with high natural or artificial radiation. a Report on food irradiation appearing in 1983, notes that development of radio-resistance by repeated irradiation "might pose a safety problem around large-scale irradiation plants."*

There are also several highly radiation resistant strains of bacteria found naturally. When food irradiation destroys other bacteria, these strains are likely to increase. Radiation resistance of bacteria of Streptococcus Faecalis or Micrococcus Radiodurans are of particular concern. No general rules can be given since there is no predictable pattern of radiation resistance.

Wholesome bacteria may be neutral or beneficial to humans.

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* Grecz, N. et al, "The Action of Radiation on Bacteria and Viruses," in PRESERVATION OF FOOD BY IONIZING RADIATION, VOL.II, CPC Press: Boca Raton, Floroda 167 (1983)

viruses are characteristically harmful. Viruses are smaller than bacteria and act as parasites at the cellular and molecular levels. Medical science is practically helpless against viral infections, which have been implicated in recent new diseases like Acquired Immune System Deficiency Syndrome (AIDS) and Legionaire's Disease.

Viruses are ubiquitous in nature and are more resistant to radiation than bacterias. They may survive for extended periods of time once in food or water, humans, animals or insects may act as carriers. The hazards of new or mutant viruses or bacteria should be addressed by further study before food irradiation is commercialized.

FOOD IRRADIATION AND NUCLEAR WEAPONS

Since the 1950's food irradiation has been and continues to be promoted primarily by the nuclear weapons bureauracy of the Department of Energy and its precedessor agencies (the Atomic Energy Commission and the Energy Research and Development Administration). Much of the research on the safety of irradiated foods has been done by the U.S. Army.

Thus, it comes as no suprise that the nuclear weapons FY 86budget for DOE contains the primary source of funds for the research, development and commercialization of food irradiation. This is because the nuclear weapons program has generated enormous amounts of intensely radioactive waste byproducts from the production of nuclear explosive materials like plutonium. At DOE's Hanford facility, 80 to 90 million curies of radiocesium has been separated and has been encapsulated for commercial use.

The desire to agressively promote food irradiation by the DOE stems from two basic factors. First, the methods of generating and storing nuclear weapons radioactive wastes have been based on expediency and not on concern for the long-term consequences. The design basis for DOE's high-level radioactive waste management is in excess of 30 years old and is dangerous and obsolete. The costs required to correct this very serious problem are large. For example, in 1979 the National Academy of Sciences estimated that the high-level radioactive wastes at Hanford could be solidified in glass at a cost of $40 billion. It is clear that if forced to internalize the costs of past mistakes, such as the Hanford wastes, this could significantly alter the economic equation of nuclear weapons production.

Instead of dealing with this problem in a responsible manner, the DOE is attempting to pass on the costs of their nuclear wastes to the rest of society. Thus, by ridding themselves of a large amount of radiocesium for food irradiation, the DOE does not have to spend money to properly stablize this particularly dangerous substance and prepare it for indefinite geological storage. At the same time, DOE is dramatically relaxing its internal management standards for radioactive wastes to allow high-level wastes like radiocesium to be disposed in landfills.

Under this scheme, the DOE will offer to lease its' radiocesium at a price well below the commercial price for radiocobalt. Then DOE will offer to transport the sources to and from the facilities. After the source has been spent, but is still quite radioactive, the DOE plans to return the radiocesium back to Hanford where under

under its new proposed waste standards, will allow these wastes to be dumped in shallow burial pits.

Secondly, the push to commercialize food irradiation is coming at a time when the U.S. government has embarked on a major build-up of fissile materials, above and beyond the actual arsenal demands. DOE plans to stockpile plutonium, even though there is enough plutonium in the arsenal to destroy the world many times over. The accumulation of nuclear weapons-grade plutonium will also mean the accumulation of much larger quantities of radiocesium -- the largest single radioactive constituent in reprocessed nuclear-weapons-reactor wastes. An artificially created demand for radiocesium for food irradiation will allow the DOE to have the option of pushing more radioactive wastes on to the rest of the society while it steadfastly refuses to internalize the real costs of making nuclear weapons.

ANOTHER NUCLEAR BOONDOGGLE

Just like the nuclear powered airplane, food irradiation if allowed to make it on its own in the commercial market-place would have been a footnote in a history book by the late 1950's. The viability of food irradiation has more to do with the "glacial bureaucratic drift" of the federal nuclear program than its actual need. Even if the Food and Drug Administration (FDA) issues its approval for food irradiation, this technology will not survive in the marketplace without extraordinary federal subsidies. In order to be economical food irradiation must be

done on a very large scale, which in turns requires a major market for irradiated foods. For several years, polls of the American public have consistently shown that shoppers are not interested in buying food if they know it has been irradiated. This factor alone will guarantee a tenuously small market, at best,in the U.S. for irradiated foods.

However, the Reagan administration is no doubt aware of this fact and is agressively promoting foood irradiation through its foreign aid programs, particular the Agency for International Development. Food Irradiation facilities are being planned for several developing nations which lack even a minimal regulatory program for such an ultrahazardous industry. The tragedy that occured in the fall of 1983 in Juarez ,Mexico is a clear warning of what to expect if large amounts of radioactive sources are distributed to the Third World for food irradiation. The Juarez accident involved the inadvertant grinding up of a radiation therapy machine, containing about 400 curies of radiocobalt, at a scrap yard. Science magazine described it as the worst radiological spill ever to occur in North America. Scrap yard workers were highly exposed as were entire villages where contaminated trucks passed.

H.R. 696, if allowed to pass, it will set the stage for multi-million dollar subsidies for a technology with no proven history of commercial sucess. If the lesson learned from the unfufilled promises of nuclear power are any indication, the Congress should let this bill die.

H.R. 696 IS AN ANTI-STATES RIGHTS BILL

Mr. Morrison's bill would do a number of things which not only will allow for heavy federal subsidies, but also will prevent states from excersizing their rights to protect the health and safety of their citizens from the food irradiation industry. The proposed legislation forbids state and local governments from regulating food irradiation independently and forbids them from requireing consumer labeling or other consumer protection not required under federai law.

This bill goes against the consistent trend of federal legislation in the nuclear area which has broadened state powers. These laws include the 1977 amendments to the Clean Air Act which allow states to set stricter than federal limits for airborne radioactivity, the Nuclear Waste Policy Act of 1982 which gives the states consultation and concurrence and vetos powers over high-level nuclear waste sites, the 1984 reauthorization of the Resource Conservation and Recovery Act which gives states the power to regulate non-radioactive toxic discharges at nuclear sites. Additionally, the courts have reconfirmed the constitutionality of state powers over the nuclear industry. In California V. U.S. (1983) states have the power to prevent nuclear power plant construction on economic grounds. In Silkwood v KerrMcGee (1984), states have the right to excersize the tort laws to impose punative damages on nuclear facilities which pose threats to communities.

In the area of transportation, there are over 200 state and local ordinances restricting or regulating nuclear cargo shipments.

There is a reason for this important trend of states imposing their powers on the nuclear industry. It has to do with the failure of the federal government to carry out its stewardship obligations to protect public health and safety from nuclear activities. The Morrison bill is merely another attempt by the federal nuclear program to reverse this trend.

COMMENTS OF

KATHLEEN M. TUCKER* AND ROBERT ALVAREZ**

ON

PROPOSED REGULATIONS

ON

IRRADIATION IN THE PRODUCTION, PROCESSING,

AND HANDLING OF FOOD

FDA DOCKET NO. 81N-0004

May 16, 1984

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Comments on Proposed Regulations on Irradiation in the Production, Processing, and Handling of Food, FDA Docket No. 81N-0004

INTRODUCTION

The following comments are presented jointly by Kathleen M. Tucker, President of the Health and Energy Institute, and Robert Alvarez, Director of the Nuclear Power and Weapons Project of the Environmental Policy Institute.

The Health and Energy Institute is a non-profit public interest organization with a membership of around 8,000. Founded in 1978, the Health and Energy Institute engages in research, education, and training. It has a scientific advisory board with expert in both the physical and biological sciences as well as several physicians. It promotes public policies which protect the environment and enhance human health.

The Environmental Policy Institute (EPI) is a non-profit, public interest organization engaged in research, public education, litigation and lobbying. EPI influences national policy on energy and the environment by anticipating and responding to environmental threats of local, national and international significance. EPI is a nationally respected source of information used not only by local citizen organizations but also by government, industry, labor and the media. EPI helps citizens influence policies affecting their daily lives by informing them when and how their views can be most effectively voiced in Washington. EPI forges national consensus on public policies by building winning coalitions that are economically, politically, and geographically diverse.

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I. SUMMARY AND RECOMMENDATIONS

Food Safety

Despite over twenty-five years of research and tens of millions of tax dollars spent on developing food irradiation as a preservative, there are disturbing scientific findings and major uncertainties relative to food safety. Observations that gamma irradiation of grains and vegetables stimulates the production of highly toxic and carcinogenic aflatoxins which are some 1000 times more carcinogenic than EDB (according to the EPA), is sufficient evidence to reject gamma sources and to find more suitable alternatives. The production of free radicals creating radiolytic products in irradiated food appears to be related to significant offspring effects in animal feeding studies. The possibility that food irradiation may spawn radiation-resistant strains of bacteria and viruses is not an insignificant problem to the society. Also improperly monitored and calibrated machines could induce radioactivity in foods.

The problems surrounding the safety of irradiated foods are to a major extent due to a lack of credible research. In 1968, the FDA rejected the Army's research on irradiated pork on grounds of possible adverse health effects to food consumers. In the 1970s, the Army then contracted out their research to IBT (Industrial Bio-Test), a company whose officials in 1983 were

convicted of performing fraudulent safety research for industry and government. More recently, research supervised by the USDA suggests adverse offspring effects to animals fed gamma-irradiated chicken.

Health and Environmental Impacts

The implications of food irradiation technologies on public health and the environment could be quite serious, particularly from gamma sources. The Energy Department, which is the largest subsidizer of food irradiation, is working to undercut all other modes by leasing cesium-137 sources at 10 cents per curie, undercutting the market rate of $1.00 a curie for other gamma sources. In all likelihood there could be a quantum jump in the volumes of highly dangerous radioactive by-products moving on U.S. highways for use near population centers and food growing areas. There are plans to build a Hawaiian food irradiator right at the Honolulu International Airport. One food irradiation facility using a 3 million curie radiocesium source could have a radiation through-put every 5 years of 450,000 curies going in and out of the plant. This is about 5 times greater than the total volume of low-level radioactive wastes generated in 1981 in the United States from all sources. This is a particularly critical problem in the absence of effective regulation by the Nuclear Regulatory Commission, the Department of Transportation, and the states.

Concern over this problem has prompted over 200 local communities to impose bans or restrictions on nuclear cargo transportation in defiance of federal preemption.

The record of keeping track of radiation sources leaves much to be desired. Numerous incidents over the past few years have been reported where sources were simply "lost," or were found by children in public, unrestricted areas where sources were accidentally mixed in with scrap metal, and where offsite contamination from radiation byproduct facilities resulted in widespread contamination. If the federal government cannot keep track of the some 17,000 sources in the U.S., what can we expect when millions of curies are added to the commercial sector?

There also appear to be non-radiological toxic problems associated with the irradiation industry. At least one irradiator, Radiation Technology Inc. of New Jersey, maintains a toxic waste dump designated by the EPA to undergo remedial action under the Superfund Program.

Occupational exposures at irradiation facilities are considered by the NRC staff to be the most hazardous in the radiation by-product industry. There have been several overexposures involving gamma sources such as those proposed to be used for food irradiation. Moreover, abnormally high cancer mortality now being observed among federal radiation workers

suggests that current standards are inadequate to protect workers.

The use of gamma sources for food irradiation in developing countries poses even more serious problems relative to health and safety -- as witnessed by what Science magazine deemed to be the worst radiological accident ever to occur in North America, when some 400 curies of radiocobalt were ground into scrap metal and then sold in Mexico and the U.S.

Recommendations

I. Environmental Impact Statement

We recommend that an environmental impact statement be filed before further action is taken on the proposed regulations. The environmental impact statement should include an evaluation of:

A) Impact of increased circulation of the gamma-source radioisotopes (cobalt-60 and cesium-137) to be used in proposed food irradiation facilities, including transportation and ultimate disposal.

B) Potential impact of increased aflatoxin production due to food irradiation.

C) Potential impact on bacteria in food or the environment due to operation of food irradiation facilities, including mutant bacteria.

D) Potential impact on viruses in food and the environment.

2. Re-evaluation of federal regulatory capacity to assure the safe functioning of food irradiation facilities and to assure the safety of the work force.

3. Continuation of the current requirement that all foods which have been irradiated and all foods whose constituents have been irradiated be labeled for the consumer with the words, "treated with ionizing (or 'gamma' or 'election') radiation."

II. FOOD SAFETY

For over twenty-five years the federal government, principally though the U.S. Army Quartermaster Corps, has performed the bulk of the research relative to the safety of irradiated food. According to Sanford Miller, the food safety chief of the FDA, in a speech before the Research and Development Association (a private group which processes food for the military) on April 2, 1984, in Chicago, only three studies done over the past 25 years by the army, involving sterilizing doses

to meats, meet FDA's criteria for acceptable research. Moreover, all three studies show highly questionable findings. Studies at lesser doses are also questionable.

Despite the fact that approximately $80 million has been invested by the U.S. in food irradiation research, 1/ there are still many unresolved questions about the safety of irradiated food. The recent FDA proposal to allow food irradiation at levels up to 100,000 rads was accompanied by a press release quoting HHS Secretary Margaret M. Heckler's statement that "Thirty years of research on the irradiation process have shown that the proposed levels of irradiation are safe and nutritious." 2/ Heckler's statement is being challenged by scientists across the country.

Dr. John Gofman, Professor Emiritus of Medical Physics at the University of California at Berkeley, points out that "safe" means "involving no risk...unable to cause/trouble or damage," and concludes that our ignorance about the unidentified chemicals formed within the irradiated foods prevents a declaration of its safety. Furthermore, Gofman states, "the kind of epidemiologic study required to find out whether or not a diet of irradiated food will increase (or possibly decrease) the frequency of cancer or genetic injuries among humans simply has not been done." 3/

Dr. George L. Tritsch of Roswell Park Memorial Institute, noting the creation of free radicals in food irradiation, points out that damage to DNA by free radicals is one of the proposed mechanisms of carcinogenesis. He suggests that the risks of including molecules altered by free radical reactions in the human diet outweighs by far the benefits of the irradiation. 3/

Dr. H. W. Ibser of the California State University at Sacramento is also concerned about cancer. He states, "The fact that unidentified radiolytic products are present in irradiated foods in small concentrations is not particularly reassuring if single exotic molecules may be capable of causing carcinogenic chromosomal aberrations." 4/

Dr. Geraldine Dettman, Radiation and Biosafety Officer at Brown University, also believes that irradiation can produce "toxic or carcinogenic molecules." Since the exact effects on humans of the irradiation and the chemical changes in different fruits and vegetables cannot be determined, she urges consumer labelling of irradiated food products. 5/

Dr. Jessica Gurevitch of the Department of Biology at the University of Chicago declares, "The safety of foodstuffs treated with radioactivity has not been conclusively shown in the WHO/FAO study (1980). The long-term effects of consuming treated food have not been fully addressed; furthermore, the possibilities for

error, carelessness, or even sabotage in the irradiation procedure have been overlooked." 6/

The credibility of the scientific research on food irradiation effects is an important concern, since many of the studies on food safety were conducted by Industrial Bio-Test Laboratories, Inc. (IBT), a firm convicted of performing fraudulent research. Last year, IBT officials were found guilty of defrauding the government in tests of other drugs. The government uncovered such problems as failure to conduct routine analyses, premature deaths of thousands of rodents from unsanitary laboratory conditions, faulty record keeping, and suppression of unfavorable findings. 7/

On October 7, 1977, the Army declared two out of three animal feeding studies in default -- both held by IBT. IBT held contracts totalling more than $8 million to conduct animal feeding studies on beef, ham and pork. The army lost around $4 million on these defaulted contracts and 6 years of feeding study data. 8/

According to a report of the GAO issued September 29, 1978, and entitled THE DEPARTMENT OF THE ARMY'S FOOD IRRADIATION PROGRAM--IS IT WORTH CONTINUING?: 9/

A number of newspaper articles, starting in July 1976, reported serious deficiencies in IBT's testing practices. These disclosures were based on FDA's investigation of IBT. The deficiencies reported included failure to do laboratory tests which IBT reported as done; improper recordkeeping; false and incomplete reporting of test results, including animals reported as sacrificed that were still alive; and poor quality testing.

The Army finally identified similar problems with IBT's performance on the beef contract about a year later at a meeting held June 14, 1977, with the President of IBT, Dr. Joseph C. Calandra. The army discovered "missing records, unallowable departures from contract testing protocol, poor quality work, and incomplete disclosure of information on the progress of the studies." A Surgeon General official determined that the ham-pork study had serious deficiencies after the June meeting. The problems included violations of testing protocol and poor scientific techniques and judgment. 10/

IBT President Calandra is listed as the principal investigator of the 1965 study to investigate the wholesomeness of irradiated strawberries, apples and pears fed separately to albino rats. Dr. Calandra was indicted along with the three convicted IBT officials, but due to open heart surgery the judge severed his case by declaring a mistrial. IBT also conducted feeding studies on irradiated papayas in 1972. These are apparently the studies underlying the FDA safety claims for the

new disinfestation regulations. 11/ Were these studies replicated by a responsible research entity? Do we want to place our trust in research facilities that cheat?

The FDA approved an Army petition to serve irradiated bacon back in 1963, but they rescinded the approval in 1968 after examining underlying research in conjunction with a later Army petition to serve irradiated ham. They found significant adverse effects produced in animals fed irradiated food, and major deficiencies in the conduct of some experiments. These adverse effects included decreases in surviving weaned young for animals fed irradiated food, and those who ate food more highly irradiated showed greater losses of surviving weaned young. 12/

Following this setback, the Congressional Joint Committee on Atomic Energy held hearings and requested that the army provide critical source data on animals fed irradiated pork. To the surprise of the committee, army researchers claimed that this data was lost!

The only remaining government-sponsored animal feeding studies are now being administered by the USDA. Although their long awaited "wholesomeness study" has not been publically released, we have obtained it, and the findings are not encouraging.

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Since 1980, USDA has been monitoring the remaining animal feeding contract held by Raltech Scientific Service to investigate irradiated chicken. The nutritional and toxicological studies evaluated five diets: 1) Commercial laboratory diet (control group), 2) Frozen chicken (control), 3) Thermally processed chicken (control), 4) Cobalt-60 irradiated chicken, and 5) Electron irradiated chicken. One study had to be terminated prematurely due to excessive mortality among pups. The problem ocurred across all diet groups, and the cause was attributed to lactation failure. Other studies raise questions about the long term safety of gamma-irradiated chicken. 13/

In studies of mice fed test diets before birth to death or scheduled termination, survival of both sexes was significantly reduced for those fed gamma irradiated food, and that group had the highest incidence of several tumors among those analyzed. Many of the lesions which occurred infrequently (for which statistical analyses could not be performed) were found in the gamma fed group, and an increased rate of death amongst females in the gamma fed group which could not be linked to any specific lesion was noted. 14/

Male dogs fed the gamma-irradiated chicken diet had significantly lower body weights through adulthood than the dogs fed the frozen control diet, although the control dogs were

considered obese. The females fed the gamma-irradiated diet had greater fecundity than dogs on other diets. 15/

An unexplained significant reduction in the production of offspring in cultures of fruit flies reared on gamma-irradiated chicken occurred. They tried adding vitamins to the gamma-irradiated chicken and changing the basal medium, but the resulting decrease in offspring of the gamma-fed group persisted. A dose response pattern occurred with higher concentrations of gamma-irradiated chicken producing fewer offspring. 16/

Donald W. Thayer, chief of the food safety laboratory at the Agricultural Research Service of the U.S. Department of Agriculture, concludes that "two of the studies...had some possible adverse findings which will require careful consideration before the process can be declared safe." 17/

Irradiation and the Stimulation of Aflatoxin Production

According to the Environmental Protection Agency's (EPA) carcinogenic group, aflatoxin is 1000 times more potent a carcinogen than EDB. Aflatoxin occurs in nature, specifically in humid areas and tropical countries in fungus spores on grains and vegetables. Its effects on public health are considered

significant. The Food and Agriculture and the World Health Organizations of the United Nations consider aflatoxin to be a major contributor to liver cancer in the Third World.

According to a report of the FAO/WHO, "many years of research had now revealed a sufficient amount of facts about the public health problems of aflatoxins, especially with regard to their associations with liver cancer, to warrant control measures." 18/ Increased aflatoxin production following irradiation (100 Kilo-rads) of fungal spores found on foods was first reported in 1973. 19

In a series of studies published in 1976 and 1979 by researchers from the National Institute of Nutrition of the Indian Council on Medical Research, it was found that: (a) gamma irradiation of wheat at different dose levels up to 250 Kilorads showed a dose-dependent susceptibility to aflatoxin production and; (b) irradiation may enhance aflatoxins by mutating fungus spore cells or by altering or increasing fatty acid levels in the food. They also found that, at doses recommended by a joint FAO/WHO/IAEA Committee, irradiation stimulated aflatoxin production in not only wheat but also corn (31.4%), sorgum (80.8%), pearl millet (66%), potatoes (74%), and onions (84%) 20/

Ironically, since the 1950s many proponents of food irradiation have cited the role irradiation could play in ending

world hunger, particularly in Third World countries. Aflatoxin production is an even more serious problem in hot and humid climates found in many less developed nations.

Radiation-Resistant Organisms

Irradiation intended to eliminate one food hazard may intensify others. Salmonella strains infesting chicken and fish can be killed with radiation, but botulism strains that survive have less competition for growth. The more resistant botulism strains can multiply more rapidly, and since other microorganisms that make spoiling food smell bad are destroyed by radiation, dangerous fish or chicken could appear to be harmless. 21/

An extremely important environmental aspect involves the creation of new or radiation resistant bacteria through food irradiation. Radiation resistant mutants of Salmonella have been developed by repeated irradiation under laboratory conditions, and radio-resistant strains are also found in environments with high natural or artificial radiation. 22/ A report appearing in 1983 notes that development of radio-resistance by repeated irradiation "might pose a safety problem around large-scale irradiation plants." 23/

There are also several highly radiation resistant strains of bacteria found naturally. When food irradiation destroys other

bacteria, these strains are likely to increase. Radiation resistance of bacteria such as Streptococcus faecalis or Micrococcus radiodurans are of concern. No general rules can be given since there is no predictable pattern of radiation resistance. 24/

While some bacteria may be neutral or beneficial to humans, viruses are characteristically harmful. Viruses are smaller than bacteria, and act as parasites at the cellular and molecular levels. Medical science is practically helpless against viral infections, which have been implicated in recent new diseases like AIDS and Legionnaires disease. According to Grecz et. al. in PRESERVATION OF FOOD BY IONIZING RADIATION: 25/

Viruses are of special significance in radiation biology in least three respects:

1. Viral pathogens are ubiquitous in nature; the danger of food-borne viruses is ever present and must be taken into account in any food processing.
2. Viruses are as a rule considerably more resistant to radiation than either bacteria or bacterial spores.
3. Viruses have been historically the focus of intense scientific investigation in radiation biology, primarily because of their extreme structural simplicity.

Viruses may survive for extended periods of time once in food or water, and humans, animals, or insects may act as carriers. Viruses that occur in food products are easily inactivated by

conventional heat processing. But not all foods are cooked, and radiation of food is most likely to occur at low or freezing temperatures. 26/

The smaller the cell the more radiation resistant it is, but resistance may vary by as much as ten-fold. Indiscriminate irradiation of viruses might produce potentially harmful mutants of viruses. 27/

The hazards of new or mutant viruses and bacteria should be addressed in an environmental impact statement before further food irradiation is authorized.

Is It Radioactive?

The Health and Human Services press release which announced the proposed new regulations regarding food irradiation stated: "...irradiation leaves no residue in food. It does not make food radioactive, nor does it pose any radioactivity danger to the consumer." 28/ Presumably, the press release did not intend to include all levels of food irradiation as incapable of producing radiation in food, since the 1980 FDA "Recommendations for Evaluating the Safety of Irradiated Foods" states that "a photon energy of 10 MeV is near the minimum level required to induce radionuclides." 29/ Thus, irradiated food can become radioactive when treated in particle accelerators under certain conditions.

There appears to be a threshold between 5 and 10 MeV at which food can be rendered radioactive from radiation processing. Although the International Atomic Energy Agency in their Codex International claim that 10 MeV is the threshold level, Great Britain does not agree and has set their limit at 5 MeV. The FDA in their proposed rule set the limit at 5 MeV for x-ray machines and 10 MeV for electron accelerators. 30

Radiation can be induced in foods by high energy particles which are produced by linear accelerators. Photoneutron reactions are the dominant source of induced radioactivity. According to R. L. Becker, "The threshold energy for photoneutron reactions is typically about 12 MeV for lighter elements, decreasing to about 7 MeV for the heaviest elements, but with a noticeable fluctuation from element to element...."11/ When the high energy particles produced by linear accelerators strike the atoms in the food, they can dislodge neutrons from the nuclei of the atoms. The dislodged nuclei can shoot out, and some of them will be slowed down enough to be captured by another atom, making the capturing atom unstable and radioactive. Foods with a high water content are more likely to become radioactive. Foods with substantial salt content, for example ham or bacon, might be more radioactive after food irradiation for the first week following treatment. Sodium or salt in pork can absorb an extra neutron and become sodium-24, an intense gamma emitter with a half-life of about 24 hours. This food could present a hazard for food

handlers. According to one study, some isotopes which can become activated by radiation treatment have half-lives as long as 6 months (i.e., mercury). 32/

In order to make construction of irradiation facilities more economical, it has been suggested that food irradiators also be used for other purposes, such as the sterilization of medical equipment. If sterilizing medical equipment requires a capacity above 10 MeV, these facilities will present a potential for accidental overexposure. The rate of increase for induced radioactivity has been studied because it is believed possible that the energy might drift during a routine food irradiation process for at least a fraction of the time food is exposed. 33/

Presumably, the proposed food irradiation levels of 100,000 rads for fruits, vegetables, and grains would not create any substantial induced radiation. Other uses of food irradiation being studied by FDA and urged by equipment producers might raise these issues.

Radiolytic Products

Radiation processing of foods causes chemical changes in the food. Ionizing radiation forms free radicals, which are unstable and very reactive chemically. Most free radicals are short-lived intermediates, forming more stable molecules within a few

minutes. These new molecules are called radiolytic products (RP's). Scientists are debating the types of radiolytic products created. The 1980 FDA Report states that "radiolysis data available in the scientific literature are insufficient to completely catalog the identity and quantity of each RP formed in any particular irradiated food..." 14/

The FDA assessment concludes that some fraction of the radiolytic products are unique to the irradiated food, and termed them unique radiolytic products (URP's). The amount of water in a given food affects the radiolytic products, and radiolysis yields are believed to increase linearly with absorbed dose. Thus, repeated radiations would be expected to increase the total radiolytic products.

Dr. Charles Merritt has prepared a report in which he concludes that there are no "unique" radiolytic products. 15/ However, FDA researchers concluded, "Certainly some URP's will be formed which are structurally atypical of parent food molecules. Such URP's may be free radical coupling products of liquid and protein derived radicals, forming various coupling compounds, dimers, and cross-linked products. The FDA states in the Federal Register, "FDA does not believe that a substance that is a natural component of food is necessarily nontoxic." Even if no URP's were identified in a particular food, RP's formed might still be of concern. 16/

In a paper titled "Basic Effects of Radiation on Food Matter" H. Glubrecht of the Institute of Biophysics noted that formaldehyde has been observed after irradiation of carbohydrates where oxygen was present. He noted that the danger of producing cytotoxic substances like malondialdehyde seems to be slightly higher in carbohydrates. 37/ Peroxide formation can be another problem, and the higher the moisture content, the greater the peroxide formation. 38/ Benzene can be formed in irradiated beef. Irradiated meats can also produce hydrocarbons, carbonyls (aldehydes and ketones), and sulfur compounds (carbonyl sulfide, dimethyl disulfide, dimethyl sulfide, ethane thiol and hydrogen sulfide). 39/ These volatile products can be traced either to fat or protein, and they are responsible for the somewhat unpleasant odors caused by radiation. Bread prepared from irradiated wheat flour had increased pyridine in the crust that caused off-flavors and odors. 40/

Radiation destroys vitamins, especially vitamin A and its precursor, carotene, vitamin B fractions, vitamin C, and vitamin E. Radiation does not stop oxidative reactions that lead to rancidity in meat, poultry and fish, nor enzymatic reactions in these foods. 41/

Radiation processing of potatoes for sprout inhibition increases the sensitivity of the tubers to fungal attack and therefore to rotting. Internal browning can occur with onions

and garlic exposed to radiation. Radiation can cause cell death and peel necrosis in fruits like peaches, cherries, grapes, and tomatoes. Citrus fruits are rather sensitive to radiation damage, and they are more likely to bruise or to develop dark spots on the peelings after treatment. Consequently, both the Florida and California citrus growers' associations asked that the citrus products be excluded from the list of foods approved for irradiation. 42/

III. ENVIRONMENTAL IMPACTS

The preferred mode of food irradiation by the U.S. government is by gamma sources, principally cobalt-60 and cesium-137. This is because of the historic push by the Atomic Energy Commission, and now the DOE, to find ways to make money out of their enormous volumes of radioactive wastes.

The DOE is planning to lease their cesium-137 sources at 10 cents a curie -- while commercial supplies of cobalt-60 coming mainly from Canada are selling for about $1.00 a curie. Moreover, DOE is offering to develop transportation casks, and is building a major cesium irradiator in Miami which will house about 1 to 3 million curies. They are also working to build two mobile irradiators which will travel through farm areas to promote food irradiation by demonstrations. With the biggest stake in food irradiation, the DOE is spending about $15.6

million in FY 1985 directly and several million indirectly to get their radioactive wastes out into the commercial sector. 43/

DOE has separated about 90 million curies of cesium-137 and has converted it into a cloride form. Then they are encapsulating this radiocesium for use in food irradiation. All of the radiocesium prepared to date is at the Hanford Plutonium Works in Washington state. However, DOE has plans to separate radiocesium at the Savannah River Plant near Aiken, South Carolina.

If radioisotopes are used on a large scale for food irradiation, there will be a quantum jump in the amounts of dangerous radioactive materials moving on the highways and being located near population centers and major food growing areas. For example, a single food irradiation facility is expected to have about 1 to 3 million curies. If radiocesium is used, the through-put required to maintain a uniform energy field to compensate for decay (cesium-137 has a half-life of about 30 years), for the facility could be as much as 450,000 curies every five years. In 1981, all sources including the government generated only 94,000 curies of low-level radioactive wastes.

Another problem associated with radiocesium is that its chloride form is soluble in water. This poses significant problems for its storage. These radioisotopes are stored in cooling tanks. They are very thermally hot, so water must be run through the cooling tanks on a continuous basis. If the jackets around the radiocesium are defective or corrode, then the radiocesium will dissolve and potentially contaminate public and/or offsite water supplies.

Transporting hundreds of millions of curies of highly radioactive radiocesium or radiocobalt will not be welcome news to states and local jurisdictions. So far over 200 states and local governments have imposed bans or restrictions on nuclear cargo transport because of the growing concern over the federal government's inability to protect communities from hazardous cargo. 44/ The Transportation Department, for example, has fewer than 20 inspectors in the country for all hazardous cargo shipments. DOE's shipping casks which are being developed for radiocesium transport have not been tested under realistic conditions. Truck drivers and handlers are not required to be measured for radiation exposure.

IV. HAZARDS OF OPERATIONS

Radioactive Sources

Radioactive sources for food irradiators raise special hazards to the general public and the environment. Unlike machines which can be turned on and off when radiation is needed, radioactive sources like Cobalt-60 and Cesium-137 emit gamma radiation continuously. Consequently, these sources require round the clock shielding and surveillance. Critics of proposals to use gamma sources for food irradiation point out that these sources pose environmental hazards because they could be released into the environment due to transporting accidents or to "midnight dumping" when their usefullness has passed.

A variety of accidents have already occurred with medical or research radioactive sources. Sometimes radioactive sources are simply lost. A cylinder of radioactive tritium fell off of a delivery truck in Knoxville, Tennessee, in the summer of 1982. 45/ A passerby recovered a container of iridium-192 that fell off of a truck in Downey, California, in May of 1982. 46/ A cylinder containing part of a radiographic camera with Iridium-192 fell from the back of a truck in Oil City, Pennsylvania, in 1982. A man picked it up, thinking that it was a "plumbing tool," and took it home. Fortunately, he discovered its true nature before he opened it. 47/

Not all losses have occurred on the highways. On November 5, 1981, radioactive iodine being transported from St. Louis, Missouri, to Boston, Massachusetts, via American Airlines was discovered missing. 48/ Two cannisters containing radioactive iridium-192 fell off of a truck transporting them from Jersey City on September 22, 1980, in what an EPA spokeswoman described as a "somewhat routine traffic accident." However routine, authorities were initially unable to locate them, although they were eventually found intact. 49/

Two teen-agers discovered seven vials of liquid radioactive materials strewn across a muddy field in Fairfax County on February 6, 1984. The seven vials were part of a ten vial shipment from a Chicago manufacturer destined for the National Cancer Institute in Frederick, Maryland. Authorities stated that the material could be hazardous if handled improperly or if kept in clothing pockets near the body. Some of the vials contained five chemicals used for genetic research, including phosphorous-32. The vials were about the size of D-cell batteries.

The teen-agers recognized the radioactive symbol on the muddy labels, so they contacted Fairfax County police. The County policy informed the boys that the police could not act on reports from juveniles. Investigation by the authorities did not begin until one of the boys' fathers called the police. Neither

fire nor health officials were able to locate the three cylinders still missing the next day. 51/ The incident illustrates two problems of missing radioactive material: 1) What if it's never found? 2) What if local authorities are not prepared to cope with such radioactive emergencies? If these boys had not been persistent, not even seven of the vials would have been recovered. 51/

Another small boy was not so lucky. He found a cobalt-60 source in a Mexican dump, and carried the source home where it sat on a shelf irradiating his unsuspecting family. The unmarked source eventually led to the deaths of the whole family who lived in the house, including a grandmother, a sister, and a mother. 52/

Radioactive sources have somehow leaked out of both processing plants and the hospitals or research facilities where they are used. On December 5, 1981, four gallon jugs containing radioactive tritium leaked onto the sidewalk outside of the John Hopkins Hospital in Maryland. 53/ On February 2, 1982, four cannisters of cesium-137 were found destroyed in a warehouse fire at Douglas, Arizona. The cesium-137 undoubtedly became airborne, since the fire also involved various chemical explosions. 54/

The best publicized processing plant leak occurred at American Atomics in Tucson, Arizona, where an outraged governor eventually had to send in the National Guard to dispose of

abandoned radioactive tritium in 1979. 55/ The American Atomics plant was one of 17,000 facilities licensed to handle radioactive isotopes in the United States. The plant used tritium to make radioactive watch dials that would glow in the dark. Despite the dangerous nature of tritium, a radioactive form of hydrogen, the plant was located near homes, a day care center, a potato chip warehouse, and the central kitchen for the Tucson public school system!

The plant's location meant that the frequently leaked tritium ended up in the food served to 40,000 school children. In 1978 alone the plant admitted leaking 284,000 curies of tritium gas into the atmosphere. After a summer of revelations about American Atomics dumping radioactive liquids directly into the city sewer system, food in Tuscon's school kitchens that measured 2.5 times above the permissible radiation levels, high radiation levels in plants and people near American Atomics, and swimming pools 20 times hotter than EPA drinking water standards, the company surrendered its license and abandoned its factory. 56/

Governor Bruce Babbitt of Arizona described the American Atomics disaster as "a complete failure of regulation," when he used emergency powers to seize the abandoned tritium and remove it for burial as radioactive waste. In addition to the waste disposal costs, the taxpayers had to pick up the bills for food

too contaminated to eat, and area residents now face an increased risk of cancer in the future. 57/ While tritium is not used for food irradiation, the same agencies responsible for controlling tritium facilities will be charged with controlling gamma-source food irradiators. If regulatory resources were too inadequate or too compromised to police the American Atomics plant before it became a national scandal, will they prevent similar fiascos from food irradiators?

Proponents of food irradiation argue that "it can't happen here." They point out that the gamma sources (either cobalt-60 or cesium-137) are contained in rods, and cannot escape in gases or liquids as the tritium at American Atomics. But the radioactive sources must be fashioned into food irradiation equipment, and one of the plants which handles cobalt-60 has already been embarrassed by the discovery of cobalt-60 on the railroad tracks beside the Neutron Products plant in rural Dickerson, Maryland, in December of 1981. When neighbors of the plant discovered that they lived in a radioactive neighborhood, they organized to have the plant closed down. Residents learned that they are allowed to be exposed to twenty times more radiation annually from the Dickerson plant than from a nuclear power reactor under current federal standards.

Placement inside equipment does not render gamma sources safe from further accidents or releases. An old cancer therapy

machine containing an estimated 450 curies of Cobalt-60 in more than 6000 metal pellets was cut open in Mexico in late 1983. Pellets were subsequently scattered along roadways in Mexico, melted into scrap steel, or simply lost. Science magazine described the accident as "probably the worst spill of radioactive material ever in North America." 58/ At least 200 people received significant doses of gamma radiation ranging from 1 to 50 rem, including four workers who got potentially lethal doses to the whole body. Scrap metal contaminated with the cobalt-60 was fashioned into steel support rods for construction, rendering around 20 houses in Mexico and several more in the Southwest U.S. radioactive. Table bases that were shipped all across the United States gave off radiative readings and had to be recalled.

The irradiation device responsible for this havoc came from the Picker Company of Cleveland (now owned by Advanced Medical Systems) which was sold to the Methodist Hospital in Lubbock, Texas. Because this model of cancer therapy equipment developed mechanical and structural problems, the company had a policy of not refurbishing it. Although the company would have removed the source, sent it to a low-level radiation dump, and scrapped non-radioactive parts for a fee which begins at $2,000, the machine was sold to a Mexican clinic through an x-ray equipment company. The machine was never used, and eventually it ended up on a pick up truck, where it was cut open enroute to a junkyard. 59/

The radiation contamination was accidentally discovered when a truck carrying support rods manufactured from steel contaminated with metal from the junkyard set off an alarm on a unique radiation sensor at the Los Alamos National Laboratory in New Mexico. Eventually, American officials traced the Cobalt-60 to the allegedly stolen cancer therapy machine. Clean-up efforts were far from adequate, since a "hot" pick-up truck, left parked on the other side of the Rio Grande from El Paso, Texas, still tripped Gieger counters at a distance of 300 yards across the water, several weeks after the problem was first discovered. 60/ A similar kind of an accident with food irradiation gamma source equipment could lead to similar consequences and widespread contamination that is difficult or impossible to clean up. The fact that the cancer therapy machine suffered from "mechanical and structural problems" 61/ suggests that food irradiation equipment might also suffer from such problems. The cancer therapy machine was apparently sold without requiring an ultimate disposal plan, and payment for the plan, as part of the purchase price. Border patrols are not equipped with radiation sensors, so many radioactive shipments of contaminated steel entered this country before the accident was discovered. Not all of the missing cobalt-60 was recovered, and many of those exposed to radiation did not receive proper medical care.

Such accidents are not confined to foreign countries A foundry in Auburn, New York, discovered that the new molten steel

coming out of its furnace was radioactive in February of 1983. A New York Health Department investigation concluded that about 25 curies of cobalt-60 had been included in the scrap for melting. No one learned where the cobalt-60 came from, but thanks to workers who discovered something wrong with a steel thickness gauge that led to the discovery of the radioactive material, none of the contaminated metal left the plant. 62/

The problems cited above did not occur at nuclear power plants, but at sites with by-product materials or research radioactive isotopes. Between January 1 and December 1, 1983, the Nuclear Regulatory Commission (NRC) took escalated enforcement action against by-product licenses in 26 cases due to serious violations of license requirements. 63/ A 50 millicurie cesium-137 source was lost or stolen from a hospital, and cesium-137 sources were left in unlocked shields or on unattended carts at the same hospital. Radioactive trash was sent to a sanitary landfill by another hospital. The NRC attributed the problems requiring enforcement action to three common causes: 64/

1) Failure to read and understand the conditions of the license.

2) Failure to train employees in the conditions of the licensed, including the radiation safety procedures that are incorporated into the license.

3) Failure to control operations including failure of license employees to follow approved radiation safety procedures.

If license holders' staff don't read the licenses or fail to train employees in facilities handling relatively small amounts of radioactive sources, will larger facilities necessarily be operated in a safer manner?

The accident potential of large-scale irradiators are not insignificant. A major explosion at a grain elevator adjacent to an irradiator could cause a breach in the containment of an irradiator. Frequently, grain elevators suffer explosions and fires.

Food processing facilities can be expected to attract pernicious little creatures like cockroaches. Cockroaches can provide an additional mechanism of transporting radioactive materials, according to a report in the December 1983 issue of the Health Physics Journal. Author Harold Marcus reported that over a period of several years safety surveys of research labs at the Albert Einstein College of Medicine of Yeshiva University in the Bronx, New York, revealed radioactive cockroaches. In the spring of 1983, lab workers discovered roach excreta with a count rate of 250,000 cmp. Several hours later an adult roach which emitted 300,000 cpm was captured. 65/ (Release rates of 500 cpm are allowed in the nuclear industry.)

Answers to troubling questions will not be reassuring if they are based upon what has happened in the past. Can the

sources be lost? Can the sources be released accidentally? Will handlers meet the required high standards of care? Will sources be the subject of midnight dumping?

V. WORKER SAFETY

The Nuclear Regulatory Commission (NRC) staff considers occupational exposures in the irradiation industry the most dangerous in the "by-product" branch. In 1977 a worker at Radiation Technology in New Jersey accidentally opened the door to the radiation chamber when the source was exposed, receiving a 222 rem dose. This exposure level has been shown to cause serious health damage. The incident was directly caused by the management decision to allow the source to be raised with inoperative interlock and safety devices, in violation of license requirements. 66/

In court litigation between Radiation Technology, headed by Dr. Martin Welt, and the NRC, a variety of violations of NRC regulations were recited. Pool water became radioactive when a pencil containing cobalt-60 developed a loosened endcap. (Presumably a similar accident could occur in a food irradiator.)

Radioactive materials were illegally placed in a dumpster for disposal as nonradioactive garbage. Access barriers were not set up to prevent accidental entry into high radiation areas, and

radiation areas were not properly posted. 67/ Radiation Technology is responsible for a hazardous waste site in Rockaway, New Jersey, and is on EPA's Superfund list. 68/

NRC records reveal similar problems at other places. Radiographers at a field site unsuccessfully attempted to retrieve a disconnected 47 curies iridium-192 source from the radiographic device guide tube. They called in a consultant from the home office who came out and failed to start with a radiation survey. He shook the guide tube, disconnected the device, and retrieved the source. In the process, he got an estimated massive radiation dose to the finger and thumb of between 650 and 1100 rems.

VI. FEDERAL REGULATORY CAPACITY

Worker Exposures

OSHA standards would apply to worker exposure to radiation at electron beam or x-ray beam food irradiation facilities (29 CFR 1910.96). These standards are similar to those that would apply to gamma source equipment regulated by the NRC. (10 CFR Part 20) Unfortunately, OSHA does not appear to possess adequate radiation monitoring equipment or personnel to perform frequent safety inspections. Annual exposures limits for workers should not exceed 5 rems. The whole body dose expected to be lethal to half those so exposed lies somewhere between 300 and 500 rem.

The proposed regulations will allow food exposures up to 100,000 rems, so the potential for overexposure is obvious.

An NRC official visiting an irradiation facility in another country narrowly escaped an overexposure. The equipment had a light which would indicate when it was operating. Since no operator was present and the light was not on, he was urged to take a look inside. Normally cautious, the official requested prior monitoring before entry. When they returned with the monitoring equipment, they found the operator replacing the light bulb which would have warned them that the equipment was actually generating radiation. The perfection assumed in theory does not always match the reality of equipment breakdowns and human failures.

Machine Sources

While the FDA's National Center for Devices and Radiological Health sets reporting requirements for the manufacturers of products which are intended to produce x-irradiation, machines which generate electrons are not specifically listed in the regulations (21 CFR Part 1002). (Are electron generators included in the x-ray definition in practice or covered under other regulations?) These regulations address standards for the original sale of equipment. They do not provide for regular inspection of such equipment, or for re-evaluation of the

equipment if it is moved or resold. If accidental radiation occurrences are brought to the attention of the manufacturer, they must be reported to FDA. The equipment owners do not appear to have any obligation to report accidental radiation occurences. We can imagine situations in which equipment owners would be reluctant to report accidents for fear of bad publicity or liability for damages.

The regulations address special requirements for products which might display aging effects, but they do not suggest any provisions which would require retirement of such equipment when its useful life has expired. Manufacturers and dealers are only required to preserve records for 5 years, although it is quite probable that expensive food irradiation equipment will be expected to last longer than 5 years and that equipment failures might not be apparent before five years.

Minimum Levels of Training

FDA is not proposing any requirement that equipment operators possess even minimal training in "radiation health physics, dosimetry, worker safety, and proper record keeping." We consider this failure to set at least minimum training criteria totally irresponsible. Machine sources of electron beams or x-rays need highly trained operators, and operators for all food irradiation equipment must be knowledegable about these

issues if they are to ensure the safety of the workplace and the food product. Under the proposed regulations, a Spanish-speaking migrant worker could legally be placed in charge of food irradiation equipment with English instructions. While we are not implying that food processors will be so irresponsible, we do feel it is vital that federal regulations do not encourage irresponsibility by ignoring the obvious need to require training of personnel. After all, aspects of the Three Mile Island accident in 1979 were attributed to inadequate operator training. Furthermore, the NRC has just noted that the "failure to train employees in the conditions of the license, including the radiation safety procedures" led to enforcement actions for radiography and medical licensees.

VII. Alternatives To Irradiation

The currently proposed use of irradiation for insect disinfestation of fruits and grains might be accomplished by oxygen deprivation alone for some foods. Carbon dioxide has been used successfully to fumigate stored grain products in the U.S.A. for almost two years and has been used effectively in Europe and Asia since the early 1970s. Carbon dioxide is fed into grain or rice storage bins, displacing the oxygen which insects need to survive. The grain must be held in the CO_2 solution for about four days to assure that all stages of insect life are destroyed. This treatment is apparently an economical non-toxic alternative

to chemical fumigation treatments, and no new chemical pollutants are added to our environment. 69/ A flexible membrane storage system being promoted by Agristore Systems accomplishes insect disinfestation by sealing grains within a high tensile strength liner and woven cover coated with polyvinylchloride. The increased level of CO2 and the natural respiration of the grain reduces the oxygen level so that insects suffocate. 70/

VIII. CONSUMER LABELING

The FDA proposals would keep a controversial food process secret from the public. It would eliminate the current requirement for consumer labeling of irradiated food with the words "treated with ionizing (or 'gamma' or 'electron') radiation" (21 CFR 179.22(c) and 179.24(d). Several arguments have been offered for keeping food irradiation secret from the public: 1) It's not a food additive, but a process, 2) Consumers will erroneously think the food is radioactive, 3) It's safe, and 4) The subtle argument that the public doesn't need to know how their food is treated if some "experts" have sanctioned it.

It's a Process

Food irradiation is a process which can change the food we eat. One can argue that the creation of radiolytic products makes it similar to an additive, since new chemicals end up in

the food. When Congress required the labeling of irradiated foods, it was more concerned with informing the public than scientific accuracy in wording. Whether it's an additive or a process, the fact that food was irradiated should be communicated to the public.

There are other food processes which require labeling, such as pasteurization of milk. The label is required because that process is not readily obvious to the consumer. Foods which have been canned are sold in sealed cans or jars. Frozen foods are kept in the freezer section of the grocery store, so the consumer can determine that the food is frozen. The irradiation process will not be evident from storage site at the market, yet the consumer has a right to know how food being purchased has been treated. The existing labeling requirement enables the consumer to determine how food has been preserved, just as labeling requirements enable consumers to determine what preserving additives are placed in food. We oppose the proposal to eliminate consumer labeling for irradiated foods.

Radioactivity

The FDA has echoed the irradiation industry argument that consumers will falsely think the food is radioactive if the food is labeled. If there are consumers who are confused or misinformed, keeping a food process secret will not eliminate

confusion or misinformation.

A review of comments appearing on the FDA record indicated consumer concern that food might become radioactive due to accidents. Over-exposures by machine sources or accidental leaks from gamma sources could conceivably occur. Past contamination of feed grains with PCB's have made the public cautious about their food.

Safety

The FDA states that since food irradiation is safe, it needn't be labeled. It is the responsibility of FDA to prevent unsafe additives or processes. Thus, only safe additives or processes would be labeled for the consumer. Labeling provisions are intended to help consumers make informed choices. People allergic to certain food ingredients can thus avoid foods with such ingredients. People who simply wish to avoid certain additives can thus avoid them. People who want certain ingredients or additives in their food can be asured they are present. People are rightfully asking, "If it's safe, why keep it secret?"

The Experts

Some scientific experts are praising food irradiation while others are questioning it. An International Atomic Energy Agency (IAEA) document is cited by the FDA regarding food safety and recommending no labeling. The mandate of the IAEA is the promotion of radiation technology, not the protection of the environment or the promotion of public health. Consumers have the right to determine which experts they trust regarding the safety of irradiated foods.

The FDA should not dismiss the Congressional mandate to label irradiated foods at the retail level. The FDA should not adopt some euphemism designed to hide the fact of ionizing radiation, but should retain existing labeling requirements.

TUCKER-ALVAREZ COMMENTS FOOTNOTES

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2/ Health & Human Services press release: HHS NEWS (Feb. 14, 1984).

3/ Gofman, John, M.D., "Invited Comments on Food Irradiation and Labeling" FDA Docket No. 81N-0004 (February 28, 1984).

3A/ Tritsch, George L. "Comments on Docket #81N-0004."

4/ Ibser, H.W., "Comments regarding FDA's proposed new regulations for commercial food irradiation," FDA Docket No. 81N-0004 (April 3, 1984).

5/ Dettman, Geraldine, "Comments regarding Docket No. 81N-0004" (April 10, 1984).

6/ Gurevitch, Jessica, "Comments regarding FDA Docket No. 81N-0004" (March 22, 1984).

7/ NEW YORK TIMES, p. 1 (Oct. 22, 1983), and WASHINGTON POST, p. A7 (Oct. 22, 1983).

8/ GAO, The Department of the Army's Food Irradiation Program--Is It Worth Continuing? PSAD-78-146,13-15 (Sept. 29, 1978).

9/ Id at 19.

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11/ Op. cit. 7, NEW YORK TIMES, and International Project in the Field of Food Irradiation, p. 136.

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FOOD IRRADIATION HAZARDS

TESTIMONY OF
KATHLEEN M. TUCKER, ESQ.
PRESIDENT
HEALTH & ENERGY INSTITUTE

BEFORE THE
SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH, & FOREIGN AGRICULTURE
OF THE HOUSE COMMITTEE ON AGRICULTURE

NOVEMBER 18, 1985

Thank you for the opportunity to testify before your subcommittee this morning regarding the hazards of food irradiation. We are appalled by Food and Drug Administration (FDA) proposals to allow secret irradiation of our fresh fruits, vegetables, and grains with ionizing radiation either from gamma sources like cobalt-60 or cesium-137 or by machine sources of x-rays or electron beams. Our concerns are listed in great detail in the Comments which the Health & Energy Institute and the Environmental Policy Center submitted to the FDA and which we have provided to this subcommittee. We respectfully request that these Comments be made part of this hearing record.

The Health and Energy Institute is a non-profit, public interest organization, founded in 1978, which addresses a variety of nuclear and environmental issues. The Health and Energy Institute opposes HR 696, the Federal Food Irradiation Development and Control Act of 1985, because it is economically unsound, infringes on states rights, and promotes an unsafe technology which can endanger both human health and our physical environment.

FOOD IRRADIATION IS NOT ECONOMICALLY SOUND

Using ionizing radiation to preserve food is like using a chain saw to cut butter. Our federal tax dollars should not be wasted promoting such a technology, as sought by HR 696. Back in the 1950's there was great enthusiasm for the "peaceful atom," and the Atomic Energy Commission promised that nuclear generated electricity would be too cheap to meter. Tax dollars were invested in developing a nuclear powered airplane, atomic furnaces that would both heat the home and melt the snow off the sidewalk, and even atomic toasters.

The electrical nuclear power industry has proven exorbitantly expensive, and some utilities fear it will bankrupt them. The tremendous shielding required to protect a pilot in a an airplane fueled by fission doomed the project. It was like trying to paste wings to an elephant and expect it to fly. The atomic home furnace would not only melt the snow off the sidewalk, but also melt the inhabitants. There have already been many such atomic technological dead ends.

The food industry is the largest industry in the world. It traditionally researches and develops food processing and preservation methods on its own. The industry explored the potential of food irradiation back in the 1950's, but dropped their research because the process was too expensive, the food didn't taste very good, alternatives like refrigeration and freezing were far more promising, and some companies felt that irradiation had been oversold. 1

Irradiated food will be more expensive. Extending the shelf life of chicken or fish an extra week could cost around five cents more per pound. Food irradiation will require greater centralization of food processing, because food irradiation facilities are capital intensive ventures. Noel F. Sommer of the University of California at Davis, a postharvest pathologist, notes that costs of a facility must also include such items as refrigeration and transportation of produce to and from facilities. Promoters sometimes pull their figures out of the air," he warns. "Often these figures have been greatly underestimated. 2

Writing to the FDA in June of 1981, Griffith Laboratories U.S.A., a food processor, pointed out that "according to published figures, radiation processing of spices would be approximately three times as costly as current acceptable processes....We do not see any favorable economic benefit, but rather the reverse, especially on the small manufacturers." 3

Even food irradiation promoter Ari Brynjolfsson admits, "After all, industry does not need irradiated food." 4 Consequently, the Department of Energy is taking the lead in promoting food irradiation. In secret hearings before Congress, the Department of Energy obtained several million dollars of our tax funds to build demonstration cesium-137 food irradiators. 5 Cesium-137 is part of the nuclear waste from nuclear weapons production. In DOE's planned nuclear waste redistribution program, cesium-137 encapsulated at the Hanford site, at taxpayer expense, will be sold for less than its chief competitor, cobalt-60. Instead of leaving this dangerous isotope safely stored in one spot, the DOE will have it shipped around our nation's highways, vastly increasing the risk of accidental releases. The overburdened American taxpayer is expected to pay for this folly.

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2 Sommer, Noel, Letter to Paul T. Libassi, Editor, The Sciences, The New York Academy of Sciences, March 5, 1985.
3 Comments to the FDA re: Docket No. 81N-0004, June 19, 1981.
4 Brynjolfsson, Ari, "The High Dose and Low Dose Food Irradiation Programs in the United States of America," in IAEA, et al., Food Preservation by Ionizing Radiation IAEA: Vienna (1978)
5 Hearings on H.R. 2496, Department of Energy National Securities and Military Application of Nuclear Energy Authorization Act of 1984 before the House Procurement and Military Nuclear Subcommittee of the Committee on Armed Services, House of Representatives, 98th Congress, March 1 & 2, 1983.

Tax dollars should not be used to subsidize industries that will make our foods more expensive and require greater centralization of the food distribution system. Tax dollars can be spent more wisely to aid farmers instead of middlemen in the American market.

HR 696 CURTAILS STATES RIGHTS

HR 696 will change current law so that labeling of irradiated foods to the consumer will no longer be required by the Federal Food, Drug, and Cosmetic Act. Current law treats food irradiation as a food additive, and current regulations require that food treated with ionizing radiation be labeled to the consumer with the straight forward statement, "Treated with ionizing radiation." By changing the characterization of food irradiation to a process, labeling to the consumer could be avoided, making it easier to sell irradiated food. Consumer acceptance studies have consistently shown that consumers are likely to avoid irradiated food. 6

Consumers have made it clear to the FDA that they want to know if their food is irradiated. The thousands of comments received by the FDA in response to their proposed rulemaking overwhelming opposed secrecy in labeling. Both the states of Oregon and Vermont are considering legislation to require that irradiated foods be labeled.

HR 696 forbids state and local governments from regulating food irradiation independently of the federal government, and forbids them from requiring consumer labeling or other consumer protection not required under federal law. This is an outrageous effort to shield a dangerous technology from elected officials who try to protect their constituents. Consumers should be given the opportunity to avoid irradiated food, because serious questions have been raised by reputable scientists about consuming such food.

HAZARDS OF EATING IRRADIATED FOODS

The safety of consuming irradiated foods is open to serious doubt. Many scientists from colleges and universities across this nation have urged the FDA to delay action on irradiated foods until more is known about the hazards. Scientific studies have already demonstrated such problems as:

1. The loss of vitamins and nutritional quality in foods which are irradiated.
2. The potential for genetic damage and cancer resulting from eating irradiated foods.
3. Increased growth of naturally-occurring "aflatoxins," which are potent cancer-causing agents, due to the irradiation process.

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6 Marketing and Consumer Acceptance of Irradiated Foods, Report of the Consultants' Meeting on Marketing, Market Testing and Consumer Accpetance of Irradiated Foods, Organized by the Joint FAO/IAEA Division of Isotope & Radiation Applications of Atomic Energy for Food & Agricultural Development, Vienna, 27 September--1 Ocitober 1982.

4. Creation of new chemicals in the food, called "radiolytic products," by the ionizing process.
5. Increased risk of food poisoning caused by the radiation resistant botulism bacteria.

We are also concerned about environmental hazards related to the food irradiation process, including:

1. The increased risk of accidental contaminations caused by plant operations with radioactive sources and the greatly increased transport of these dangerous radioisotopes.
2. The possible creation of dangerous mutant bacteria or viruses during the irradiation process. Proposed doses for use in the United States are not sufficiently high to kill off all organisms, so they can mutate and survive.
3. The increased generation of radioactive wastes, for which storage problems are already severe.

Today's testimony will focus on our safety concerns, as others will address environmental concerns.

The FDA discounted the need to determine the overall effects on a diverse population of eating a variety of irradiated foods over a lifetime. The FDA declared irradiated food safe by ignoring the evidence of a variety of scientific studies. An FDA memorandum dated April 9, 1982, states that a Task Force reviewed 441 studies and initially accepted 266. Using certain criteria, they eliminated many studies, and examined in detail 32 studies indicating adverse results of eating irradiated foods and 37 studies that appeared to support safety. Next they declared all but five studies (which supported safety) "deficient." 7 We do not think it is appropriate to base the safety of a hazardous process on five studies, ignoring a vast literature containing evidence suggesting that irradiated foods may be hazardous to our health.

In a review of 1223 wholesomeness studies conducted by J. Barna for the Hungarian Academy of Sciences in 1979, study results were classified as either neutral, adverse, or beneficial. Each study could have several outcomes, since studies could address more than one issue. Barna found 1,414 adverse effects, 185 beneficial effects, and 7,191 neutral effects. Clearly, there is research evidence suggesting potential harm to humans.

Barna provided breakdowns for items considered, and I'll provide some examples. For bacon, he found 86 neutral study results, 31 adverse study results, and no beneficial results. For soybeans he found 60 adverse study results, no beneficial results, and 26 neutral study results. For sucrose he found 39 adverse study results, 38 neutral, and 1 beneficial. For corn oil he found 13 adverse, 5 neutral, and no beneficial results. 8

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7 Food & Drug Administration Memorandum, Final Report of the Task Group for the Review of Toxicology Data on Irradiated Foods, April 9, 1982.
8 Barna, J., "Compiliation of Bioassay Data on the Wholesomeness of Irradiated Food Items," Acta Alimentaria Vol. 8 (3) pp. 205-315 (1979)

The studies reviewed by Barna were those considered by a so-called "expert committee on wholesomeness" sponsored by the International Atomic Energy Agency and others. This so-called expert committee declared irradiated food safe. The International Atomic Energy Agency is not a public health organization; its mandate is to promote nuclear technologies. We contend their declaration of wholesomeness is analogous to claims by the American Tobacco Institute that cigarette smoking has not been proven dangerous to one's health.

I would like to draw the subcommittee's attention to a couple of studies indicating adverse effects to support our overall concern.

In a study on feeding freshly irradiated wheat to malnourished children, conducted in India, children fed freshly irradiated wheat developed blood abnormalities (polyploid cells associated with cancer induction), while control children fed the same diet did not show this problem. The study was published in a refereed scientific journal, The American Journal of Clinical Nutrition. 9 Food irradiation promoters have suggested that the study was fraudulent, and they claimed it was repudiated by the director of the Institute conducting the study. We wrote to the Institute, and we have attached their response, which indicates that they stand behind their study. In fact, similar problems with freshly irradiated wheat have been demonstrated in the blood of both monkeys and mice. 10

Another study looked at drosophila melanogaster (fruit flies) for genetic damage when fed irradiated chicken. 11 That study found that fruit flies fed gamma irradiated chicken had seven times fewer offspring than those fed thermally processed chicken. Donald W. Thayer of the Department of Agriculture considered this finding alarming, and worthy of further investigation.

Studies which we have reviewed indicate that different chemical products are formed in different foods, and there can even be differences between the same types of foods. We believe that the scientific literature thus far creates controversy over the safety of feeding irradiated foods to our children. We therefore recommend the following:

1. Commercialization of food irradiation should be halted.

2. An environmental impact statement should be prepared for the food irradiation process before more funds are committed or spent for development in this field.

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9 Bhaskaram, C. & G. Sadasivan, "Effects of Feeding Irradiated Wheat to Malnourished Children," 28 American Journal of Clinical Nutrition pp. 130-135 (Feb. 1975)

10 Vijayalaxim, "Cytogenetic Studies of Monkeys Fed Freshly Irradiated Wheat," 9 Toxicology pp. 181-184 (1978)

11 Raltech Scientific Services, "Evaluation of the Mutagenicity of Irradiated Sterilized Chicken by the Sex-Linked Recessive Test in Drosophila Melanogaster," Final Report, Contract #DAMD-17-76-C-6047, submitted to the U.S. Army Medical Research and Development Command, Fort Detrick, Frederick, MD (November 9, 1979)

3. The many unanswered questions about the safety of eating irradiated foods should be addressed by agencies that do not promote nuclear technologies.

4. HR 696 should not be passed into law.

5. Any food or food ingredient that has been irradiated with ionizing radiation should be clearly labeled to the consumer as required by current regulations.

(Attachments follow:)

Food Irradiation: An FDA Report

by Alan T. Spiher, Jr.

The potential of ionizing radiation as a food processing technique has been of major interest to both Government and industry for more than two decades, but experimental work with irradiated foods has shown that there are still significant questions concerning the safety of the proposed uses.

The Food and Drug Administration is responsible for protecting the public from harmful and adulterated foods, drugs, and cosmetics through the Federal Food, Drug, and Cosmetic Act. FDA's jurisdiction over irradiated food and sources of radiation intended for use in producing, packing, and transporting food derives specifically from the Food Additives Amendment to the Act. Congress provided thereby in 1958 that a food is adulterated if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a specific regulation or exemption. The food additives section sets forth the requirements for a petitioner to obtain such a regulation prior to marketing the product (FDA PAPERS, May 1967).

Among other things, a proponent of food irradiation must provide adequate and sound scientific evidence that the proposed use is safe and will accomplish the intended technical effect.

Recently, FDA advised a petitioner that the Agency cannot take favorable action on his petition for irradiated ham. Based on data supplied in the ham petition, FDA also has proposed to rescind existing regulations that permit radiation processing of canned bacon.

A careful analysis by FDA of all data presented (including 31 looseleaf notebooks of animal feeding test results) showed (1) significant adverse effects produced in animals fed irradiated food, and (2) major deficiencies in the way some of the experiments were designed and conducted.

What were these adverse effects?

1. Rats were fed diets containing approximately 35 percent bacon and approximately 35 percent fruit compote, both in the same ration. Nine different diet combinations were made up by one or both of the test foods being irradiated at any one of three levels: 0 megarads (controls), 2.79 megarads, or 5.58 megarads. Rats fed test diets containing bacon irradiated with a 5.58 megarad dose combined with the fruit compote portion irradiated at 0, 2.79, and 5.58 megarads exhibited a 13.68 percent decrease in surviving weaned young for each mating when compared with the animals on the control diet containing unirradiated bacon and unirradiated fruit compote.

Because irradiated compote might enhance or diminish the effect of irradiated bacon in the diet, the rats that consumed only irradiated bacon and unirradiated compote were compared with those consuming diets containing only unirradiated bacon and unirradiated compote. The animals on the diet containing bacon irradiated with a 2.79 megarad dose showed a decrease of 20.7 percent in surviving weaned young when compared with the animals on the unirradiated diet. The animals on the 5.58 megarad-treated bacon showed a decrease of 28.7 percent in surviving weanlings. Such reductions are highly unlikely to be due to chance.

2. Five experiments with rats fed irradiated pork produced mixed results. One, completely reported, showed no adverse findings. This involved feeding pork at 35 percent of the diet with the pork irradiated at 0 (controls), 2.79 megarads, and 5.58 megarads. One experiment with cooked pork was so incompletely reported that evaluation was impossible.

One experiment with rats fed with ground pork constituting 60 percent of the diet, irradiated at 2.79 megarads, showed a reduction in live weanlings and a reduction in the weight of the weanlings at 33 days when compared with the control animals on the unirradiated diet.

One experiment involved feeding diets with 35 percent frozen pork and irradiated with a dose of 2.79 megarads or 5.58 megarads. The numbers of weaned progeny per litter and mean weight of progeny were reduced by comparison with control animals.

One experiment involved feeding an organ mixture containing 9 percent pork kidney at 60 percent of the total diet and irradiated at 2.79 megarads. There were discrepancies in the reported data and arithmetic errors. However, a depression in the body weight of the offspring was reported. At 28 days after birth, the weight of the test group was 11.65 percent less than that of the control group and at 33 days after birth, the reduction was 9.35 percent.

3. Dogs fed a diet containing 35 percent pork irradiated at 5.58 megarads exhibited a highly significant 32.3 percent decrease in surviving progeny from the number of surviving progeny of the animals on the control diet containing 35 percent unirradiated pork.

4. One strain of mice fed diets containing 10-20 percent bacon lipid irradiated at 5.58 megarads weighed an average of 1.2 percent less after 1 month, and 6.0 percent less at the end of 18 months than did animals fed corresponding diets containing unirradiated lipid. A second strain of mice on the diet showed 3.4 percent less after 1 month and 17.6 percent less at the end of 18 months.

5. Dogs on diets containing 35 percent bacon ir-

radiated with a 5.58 megarad dose weighed 5.8 percent less on the average at the start of an experiment than did the dogs on unirradiated control diets. After 105 weeks on the irradiated diet, the dogs weighed 11.3 percent less on the average than the animals on the control diets.

6. Rats fed a diet containing 35 percent bacon irradiated at 5.58 megarads with 35 percent unirradiated fruit compote exhibited a greater cumulative mortality than the animals on the control diet with both bacon and compote unirradiated, beginning between the 49th and 59th week of the test. All of the animals on the irradiated diet had died by the 104th week on the test diet compared with only 83 percent of the animals on the unirradiated combination.

7. Data on rats fed both irradiation levels of bacon and fruit compote suggested that malignant tumors may be associated with irradiation of bacon or of fruit or of both. Malignant tumors were reported in eight of the 254 animals on the irradiated test rations but none was found among the 77 animals on the unirradiated control diet.

8. Three of 104 rats fed diets containing pork irradiated at 2.78 or 5.56 megarads developed carcinomas of the pituitary gland. None was reported in 52 control animals. This was a particularly disturbing finding since this is an extremely rare type of malignant tumor.

What were the deficiencies in experimental design and execution?

FDA's evaluation of the submitted data showed major deficiencies in the design and execution of the petitioner's irradiated food studies. His test foods were irradiated under conditions quite different from those now expected to be used commercially.

The petitioner used spent fuel rods for irradiation instead of the cobalt-60 or cesium-137 sources requested in the petition to FDA. FDA has received no data to show whether or not the chemical changes produced in food by the mixed radiation from fuel rods are comparable to those produced by the gamma radiation of pure cobalt or pure cesium. Nor did the petitioner present data to show that the test foods received the doses claimed.

The various investigators for the petitioner used comparatively small numbers of experimental animals in chronic feeding studies, particularly in those with dogs. When small numbers of animals are used in toxicity experiments, virtually any difference in response between test and control animals may be insignificant in a statistical sense, but may be of considerable concern when viewed in terms of potential health problems.

Alan T. Spiher, Jr., is a Food and Drug Officer in the Petitions Control Branch of the Bureau of Science. He joined FDA in 1941.

Further work also is needed to explain the aberrations in performance and condition of animals on irradiated diets which some of the investigators attribute to "marginal nutritional inadequacies." Such a conclusion appears untenable because the animals were administered amounts of nutrients well in excess of the total requirements and no analyses were performed on the diets as administered to the animals.

The petitioner's investigators appear not to have pursued the indication in some studies (including those employing enzyme systems) that an antinutrient factor may be produced by irradiation. There are also indications that this factor may affect unirradiated nutrients administered to the animal separately from the irradiated portions of the diet.

Although a number of scientists have made suggestions that the risk of tumor formation may be enhanced by the irradiation of food, the petition on ham did not include an adequate pathological examination of tissue for tumors. The bacon study involved 222 rats for which no tissue was examined for tumors or other lesions. Nor was information presented on gross postmortem observations of these animals.

Similarly, the petitioner apparently conducted an inadequate pathological examination on the eyes of experimental animals despite the reported increased risk of cataract formation in rats fed irradiated bacon. Data on eye changes submitted so far have been of questionable reliability.

Adding up the foregoing comments on the experimental studies, it is clearly apparent that the FDA cannot conclude that the irradiation of ham (and bacon) has been shown to be a safe process. On the other hand, the FDA scientists are not in a position to conclude that all conditions of processing by irradiation would produce an unsafe food. Certainly the door is still open to further consideration on the basis of additional studies designed to answer the several questions which have been raised so far.

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Date: October 30, 1985

To: Those Concerned About Food Irradiation

From: Kitty Tucker

Re: DOE Food Irradiation Demonstration Projects

The Department of Energy (DOE) is developing three food irradiation facilities according to Mr. Bill Remini of the DOE Byproducts and Utilization Branch. Funds for the program were apparently authorized in 1983, after they were proposed in secret hearings of the House Procurement and Military Nuclear Systems Subcommittee of the Committee on Armed Services. According to Remini, five million dollars was authorized for development, but DOE staff and overhead figures are not included, as they are part of the overall division budget. (See Hearings on H.R. 2496, Department of Energy National Securities and Military Application of Nuclear Energy Authorization Act of 1984 before the Procurement and Military Nuclear Systems Subcommittee of the Committee on Armed Services, House of Representatives, 98th Congress, Mar. 1 & 2, 1983.)

The food irradiators plan includes one transportable unit destined to travel through the Pacific Northwest, one Commodities Irradiator destined for downtown Dublin, California, and a pork irradiator for which site selection is only now under way. The irradiators will use DOE produced cesium-137, a dangerous gamma emitter with a half-life of 30 years. Since cesium-137 is water soluble, a release of radioactivity into the environment from either a transportation accident or a plant release could irrevocably contaminate the groundwater. Cesium-137 is a waste product of plutonium production for the nuclear weapons program at the Hanford Nuclear Reservation in Washington State.

TRANSPORTABLE CESIUM IRRADIATOR (TPCI, pronounced "Tipsy")

TPCI is being constructed and assembled by Foster-Wheeler as the prime contractor. The plans for this movable unit are being reviewed by the DOE nuclear safety committee. Although it is hoped that the unit can eventually be turned over to private industry, no NRC license has been sought. A moving table will rotate food onto a carousel, the entry port will automatically seal the food inside the unit and then the unit will expose the food to gamma rays from the cesium-137 source. The TPCI unit will use a 250,000 curies source of cesium-137. (Cancer therapy machines average around 7,000 curies of radioactive materials.)

COMMODITIES AGRICULTURAL CESIUM IRRADIATOR (CACI, pronounced "Kaycee")

The CACI unit is planned as a permanent fixed irradiator destined for downtown Dublin, California. There are at least 500 homes and offices near the proposed site, which is in an earthquake prone area. The site was selected by the DOE and their private sector collaborator, the National Food Processors Association. Plans for the 3,000,000 curie cesium-137 fueled facility are being developed under contract with Rockwell International.

PORK IRRADIATOR

The DOE is undertaking competitive site selection for a pork irradiator. Selection procedures are being handled by the DOE field office in Albuquerque, New Mexico. The FDA approved the irradiation of pork on July 22, 1985, in response to a petition filed by Radiation Technology, Inc., a private company, which declared irradiation "harmless." Previous FDA approval for irradiated bacon was withdrawn in 1968 due to concerns about its safety.

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COBALT-60 FACT SHEET

Cobalt is a tough, silver-white metallic element with an atomic number of 27. Cobalt-60 is a radioactive isotope of cobalt with an atomic mass number of 60. Cobalt-60 is created by bombarding cobalt metal in a nuclear reactor. A half-life for a radioactive isotope is the time in which half of its radiation is released, and the half-life for cobalt-60 is 5.25 years. In another 5.25 years, half of the remaining energy will be released, until eventually the isotope decays to a stable element. Cobalt-60 gives off beta particles and gamma rays of high energy as it decays.

Gamma rays are very penetrating, and can pass through walls, clothing and our physical bodies. Shielding of several inches of lead or several feet of concrete is necessary to protect people from gamma radiation. Beta radiation is particulate radiation composed of sub-atomic electrons which are not as highly penetrating. Beta radiation can penetrate the outer layers of the skin, and at least a quarter inch of aluminum is required to stop it. However, the main health hazard to humans from beta radiation occurs when it gets inside the body. Beta emitters like cobalt-60 can get inside the body through the food and water we consume, through the air that we breathe, or through cuts on our bodies. Once inside the body, beta-emitters constantly bombard the surrounding tissue with radiation.

Cobalt-60 is proposed for use in food irradiators to extend the shelf-life of food by killing off insects and micro-organisms. While typical cancer therapy machines use 5,000 to 10,000 curies of cobalt-60, proposed food irradiators could contain 50 to 200times more radioactive cobalt-60 (between 250,000 and 2,000,000 curies). Most cobalt-60 used in the U.S. is produced in Canada.

Radioactive isotopes can concentrate in the food chain. The transfer factor estimates how much of an isotope is absorbed through the food chain. The Nuclear Regulatory Commission (NRC) uses a transfer factor of .00094 for the absorption of cobalt from the soil. Other scientific studies have suggested that this factor dangerously underestimates the risk. A study by R.G. Menzel (1967) found a transfer factor ranging from .02 and 2 for soil to plants. A study by W.E. Grummit (1975) found the following transfer factors for the edible parts of the following plants: oats—.015, radishes—.032, carrots—.011, turnips—.043, beans—.01, potatoes—.02, and tomatoes—.011. In view of these findings, the NRC standards have been justly criticized as inadequate.

Radioisotopes can be converted in the environment from inorganic to organic compounds which make them easier for the body to absorb. Cobalt-60 can be converted to a radioactive form of vitamin B-12, an essential nutrient usually obtained from meat and milk. NRC standards assume that no such conversion occurs, again underestimating the health impacts of the release of cobalt-60 into the environment.

Rapidly dividing cells are highly susceptible to radiation damage. That is why cobalt-60 is used in hospitals for treating the rapidly dividing cells of a cancer with an intense beam of gamma rays. This treatment must be carefully controlled, since the gamma radiation can also kill healthy cells in the body. Children are more susceptible than adults to radiation damage because their cells are dividing more rapidly, and the embryo and fetus are even more

susceptible. Cobalt-60 can be transferred to the embryo or fetus through the mother's blood stream.

Direct ionizing radiation can cause miscarriages, birth defects such as cleft palate, chronic respiratory diseases, mongolism, hypothyroidism, as well as leukemia and other forms of cancer. It apparently only takes one cell damaged by radiation to cause the later development of a cancerous tumor.

References:

Alvarez, Robert, "Radioactive Contamination in the Food Chain," Environmental Policy Institute, Washington, DC (1980).

Department of Environmental Protection of the University of Heidelberg, Germany, "Radioecological Assessment of the Wyhl Nuclear Power Plant," NRC Translation Number 520, p. 38 (May, 1978, Revised July, 1979).

Stellman, Jeanne M. and Susan M. Daum, "Work is Dangerous to Your Health," Pantheon, pp. 145-153 (1973).

Tucker, Kitty, "A Little Radiation Goes a Long Way," in Accidents Will Happen, Harper & Row, pp. 128-145 (1979).

World Book Encyclopedia, "Cobalt" and "Cobalt-60," pp. 592-593 (1980)

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CESIUM-137 FACT SHEET

Cesium is a silver-white, soft, malleable element of the alkali metal group with an atomic number of 55 and an atomic weight of 132.9. 1 Cesium-137 is a radioactive isotope of cesium with an atomic mass number of 137. Cesium-137 is a fission product created by nuclear explosions or nuclear reactors.

A half life for a radioactive isotope is the time in which half of its radiation is released, and the half-life for cesium-137 is 30.5 years. 2 That means that in 30.5 years, half of the energy of cesium-137 will be released, and in another 30.5 years half of the remaining energy will be released, and so on. Cesium-137 is considered dangerous for 300 years.

As cesium-137 decays, it gives off gamma rays of intermediate energy and beta rays of intermediate energy. 3 Gamma rays are very penetrating, and can pass through walls, clothing and our physical bodies. Shielding of several inches of lead or several feet of concrete is needed to stop gamma rays. 4 Beta radiation is particulate radiation that is not very penetrating. Beta radiation can penetrate the outer layers of skin, and at least ¼ quarter of an inch of aluminum is needed to stop it. The main health hazard to humans from beta radiation occurs when it gets inside the body; where it can constantly bombard living tissue. A mere 77 microcuries (a micro curie is one millionth of a curie) of ingested cesium-137 will result in a dose to the whole body of 10 rads in the first year. 5 (A dose of 10r is twice the dose allowed for workers and 25 times the dose allowed for the general public from the nuclear fuel cycle.)

Radioactive isotopes can concentrate in the food chain. Cesium-137 is chemically similar to potassium and will spread throughout the soft tissues of the bodies of fish, wild and domestic animals, and humans. Animals and people retain more cesium-137 than potassium, so as cesium-137 moves up the food chain, higher cesium-potassium ratios occur at each level. 6 Pathways to humans for cesium-137 include plants to cows to milk and plants to meat. Cesium-137 is likely to lodge in muscle, the spleen, the liver or other parts of the body. 7

Cesium-137 inventories in the United States have been estimated by the Department of Energy as follows:

Hanford Reservation, Washington: As of June, 1984, a total of 77 million curies existed, encapsulated in 1375 capsules. Another 38.5 million curies are projected from future Purex wastes by 1991.

Savannah River Plant, South Carolina: As of January, 1983, 102 million curies were present at the Savannah River Plant, and another 109 million curies is projected by 2001.

1 Websters New Collegiate Dictionary, pp.183 & 368 (1977).
2 V. Brodine, Radioactive Contamination, 166 (1975).
3 Ibid.
4 J. Stellman & S. Daum, Work Is Dangerous to Your Health, 147 (1973).
5 V. Brodine, op. cit. 2 at 161.
6 Ibid. at 38-39.
7 Ibid. at 168-169.

Commercial nuclear waste from electric power plants: As of January, 1983, there were approximately 102 million curies of cesium-137 in spent fuel rods. By 2020, 11 billion curies are projected. 8

8 U. S. Department of Energy, Technology Update and Future Initiatives

Radiation Technology, Inc. NUVEMBER 14, 1984

To: Dr. Ari Brynjolfsson
Dr. Charles Merritt, Jr.
Dr. Jack Schubert
Dr. Donald Thayer
Ms. Kathleen Tucker, Esq.
Mr. Clinton Miller
Dr. Julius Coon
Dr. James Dickson
Mr. Jeffry H. Reinhardt
Mr. Robert Alverez

From: Martin A. Welt, Ph.D.

SUBJECT: FOOD IRRADIATION PANEL UPDATE

Dear Panelists:

As session chairman for the panel discussion on "Alternate uses - Focus on Food Irradiation", I would like to thank you for your participation. When I was first asked to run this particular session I knew it would be a difficult assignment, and sitting at my desk the morning after, I cannot say for certain whether or not our efforts were constructive in presenting scientific concerns that one might have about consuming irradiated food. Obviously a dialogue between two points of view is a productive start. It is my intention to provide a summary of the proceedings and as such I would appreciate receiving a statement regarding the concerns you raised or the rebuttals that were given on each of the topics discussed.

With regard to our discussion on the Indian Study concerning irradiated wheat and the reported blood abnormalities, we were informed that the study in question might very well have been fraudulant. Further, a statement was made by one of the panelists that the Indian authorities at the Institute where the work was conducted have essentially refuted the concerns raised in the published study.

It was also mentioned that an Expert Committee appointed by the International Food Irradiation Project in Karlsruhe, Germany found that the study was without merit and it was pointed out that the Expert Committee report is available through Dr. Peter Elias at the Insititute Address:

Dr. P. S. Elias
Project Director
Institut fur Strahlentechnologie
PostFach 7640
7500 Karlsruhe 1
West Germany

One panelist pointed out that the Expert Review Group implied the Indian Study, using primates, pigs and rats as part of a multi generation study, was unable to verify the blood abnormalities by the Indians. One panelist indicated that only the primate study should be extrapolated to man. It was pointed out by one panel member that the expert committee reports would serve a better purpose if they had appeared in refereed scientific journals.

PROJET INTERNATIONAL EN MATIÈRE D'IRRADIATION DE DENRÉES ALIMENTAIRES
INTERNATIONAL PROJECT IN THE FIELD OF FOOD IRRADIATION
INTERNATIONALES PROJEKT AUF DEM GEBIET DER NAHRUNGSMITTELBESTRAHLUNG

Federal Research Centre for Nutrition

Institut für Strahlentechnologie
Postfach 3640
7500 Karlsruhe 1
West Germany

Miss Kathleen M. Tucker
Executive Director
Health and Energy Institute
236 Massachusetts Ave NE.
Suite 506
Washington, DC 20002
U. S. A.

20. 02. 1985

Dear Miss Tucker,

My apologies for the delay in replying to your letter of 4th January 1985 due to my repeated absences from the office.

I am afraid you may perhaps have misunderstood Dr. Welt's comment regarding an Expert Committee Report on the Indian study you quote in your letter. No such report exists, but there is a report by the 1976 Joint FAO/IAEA/WHO Expert Committee on Food Irradiation on the safety of irradiated wheat among other irradiated foods and by the 1980 Joint Expert Committee on Food Irradiation which gave full toxicological clearance to the process of food irradiation up to an average maximum absorbed dose of 1 Megarad. In these decisions the Expert Committees did take into consideration all available data including those of Bhaskaram and Sadasivan.

One of the reasons for the Expert Committee not to consider the study relevant was the curious absence of any polyploidy in the control children although there is a well-known incidence of this finding up to 4% in the general population. Moreover freshly irradiated wheat is most unlikely ever to reach the consumer in food processing practice. A repeat study with a larger number of children has never been carried out but would have resolved the issue. I am attaching some relevant papers but there are several other studies referenced, which either claim or disclaim similar findings in animal experiments. Overall those studies which have been carried out satisfactorily show no evidence to support any mutagenic or chromosomal effects of irradiated wheat, freshly treated or not.

I hope you will find these comments useful.

Yours sincerely

Prof. Dr. med. P.S. Elias

Telephone: Linkenheim (07247) — 82-4026 Telex: 07826 484

B.S. NARASINGA RAO. Ph.D.
DIRECTOR

NATIONAL INSTITUTE OF NUTRITION
Indian Council of Medical Research
Hyderabad-500 007, A.P

D/42/85/
2nd April, 1985.

Dear Dr Tucker,

Thank you for your letter drawing our attention to some remarks about the scientific integrity with regard to study on irradiated wheat in undernourished children, which you have addressed to Dr. Bhaskaram of our institute.

We are rather perturbed by the contents of your letter particularly with regard to false allegations regarding our studies on kwashiorkor children using irradiated wheat. It would be appropriate to explain why studies on irradiated wheat were taken up by the Institute to put the controversy about institute's study on irradiated wheat in its proper perspective.

A proposal was made by the Department of Atomic Energy, India, to use irradiation as a method of preservation of wheat in India. When this was referred to us we had proposed that some studies had to be undertaken, although a large number of studies earlier had established the safety of irradiated wheat because of three considerations. One consideration was that in all the previous studies, irradiated wheat was used in the test diets only to the extent of 40%, whereas in the traditional Indian diets wheat constitutes about 70-80% of total diet. Secondly, all previous studies were done with irradiated wheat which was stored for three months. Since, in view of food scarcity prevailing at that time in the country, we were concerned with the possibility of irradiated wheat being consumed without storing for 3 months, a statutory requirement for using irradiated wheat. Hence we wanted the studies to be conducted with freshly irradiated wheat also to establish their safety. Thirdly, we consider the possibility of the irradiated wheat although found safe in healthy well nourished populations, manifesting toxic effect in undernourished and malnourished population who represent a large proportion of our population. Therefore we wanted the safety of irradiated wheat to be established in malnourished population.

In view of the above considerations, we took up the studies to re-evaluate the safety of irradiated wheat under the above three conditions. A series of studies were therefore planned and carried out to test the safety of irradiated wheat under dietary and nutritional conditions prevailing in our country. Feeding of irradiated wheat to children with kwashiorkor was a part of these comprehensive studies. In light of published data we did not anticipate any adverse effects of feeding irradiated wheat to these children. However, as soon as some abnormality was observed in these malnourished children, we terminated the study for ethical reasons and the children were put on the normal therapeutic regime. We could not repeat such studies just for the sake of scientific curiosity since we knew that some abnormality (polyploidy) would result. However, a series of animal studies did indicate that when freshly irradiated wheat was fed, polyploidy

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was observed. However, when irradiated what, but stored for three months was fed, there was no polyploidy. The polyploidy disappeared after changing the diet from irradiated wheat diet to normal wheat diet. One however does not know the health significance of polyploidy. But one can assume that it represents some abnormality associated with feeding of freshly irradiated wheat although it may not result in any apparent known clinical abnormality over a period of time of one year. If law stipulates that irradiated what should be stored for three months before consumption even the doubt about the possible occurrence of polyploidy following its consumption can be avoided and one can be rest assured about its safety.

I hope the above background information puts the reported studies on irradiated wheat by NIN in their proper perspective and can strongly repudiates any unjustified allegations about the scientific values of studies of NIN which almost amounts to libel. These I presume are inspired allegations about the research findings of NIN which is known world over for its important contributions in the field of nutrition. We strongly refute these motivated allegations which cast aspersion on the scientific integrity of the institute.

With regards,

Yours sincerely,

B.S. NARASINGA RAO.

Mr. Kathleen M. Tucker
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FINAL REPORT

Evaluation of the Mutagenicity of Irradiated Sterilized Chicken by the Sex-linked Recessive Lethal Test in *Drosophila melanogaster*

Contract DAMD 17-76-C-6047

Submitted to

U. S. Army Medical Research and Development Command
SGRD-WF, Fort Detrick
Frederick, Maryland 21701

Selected Pages

By

Raltech Scientific Services, Inc.
3301 Kinsman Boulevard
Madison, Wisconsin 53707

June 15, 1979

ABSTRACT

Four samples of chicken meat, identified as FC, TP, GAM, and ELE, along with negative and positive controls, were evaluated for mutagenic activity employing Drosophila melanogaster in the sex-linked recessive lethal test. The four samples of chicken meat were determined to be non-mutagenic in the test. The positive control containing 100 ppm tris (2,3-dibromopropyl)phosphate gave a significant positive response in the test.

Reduced production of offspring in cultures reared on irradiated chicken was observed. A dose response effect was produced with gamma irradiated and frozen control chicken meat. Normal production of offspring could not be effected by changing the basal medium, adding vitamins, or using a different lot of gamma irradiated chicken meat.

The results are shown in Table 10a (page 40) and summarized in Table 10b (page 41). The addition of the vitamin supplement from Bio-Serv, Inc. at 1.3% concentration did not increase the number of offspring produced in cultures containing gamma irradiated or frozen control chicken meat. However, the addition of the vitamin supplement reduced mortality of the parent Drosophila in the negative control and in both the frozen and gamma irradiated chicken diet groups.

Summary

Based on the data that were gathered in Part II of this study the following conclusions are warranted.

1. The production of Drosophila offspring in cultures containing gamma irradiated chicken meat was much lower than cultures containing frozen control chicken meat or in those without chicken. The above findings were consistent in the two production lots of gamma irradiated chicken that were tested.

2. The production of Drosophila offspring in cultures containing gamma irradiated chicken meat was not increased by changing the basal medium or by adding a vitamin supplement to the basal medium.

3. A dose response pattern was found in Drosophila cultures containing gamma irradiated and frozen control chicken meats. The higher the concentration of chicken meat in the media, the fewer offspring that were produced. The greatest effect occurred in the media containing gamma irradiated chicken.

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Darryl Sullivan
Pesticide Evaluation Section

Robert M. Lusskin, PhD
Director, Technical Services

Gordon M. Thomson
Director, Biological Services

by and for Raltech Scientific Services, Inc.

June 15, 1979 ltm

TABLE 4

Number of *Drosophila* Offspring in Cultures Containing the Four Chicken Meat Samples (37.5% wet weight)

Compound	Number of Cultures	Total Number of Offspring	Average Number of Offspring per Culture
Negative Control (no chicken meat)	17	12,251	720.6
Frozen Control Chicken	22	7,320	332.7
Thermally Processed Chicken	17	6,874	404.4
TRIS (@ 100 ppm) Positive Control (no chicken meat)	12	3,239	269.9
Electron Irradiated Chicken	23	3,680	160.0
Gamma Irradiated Chicken	28	1,599	57.1

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TABLE 5

Comparison of Two Lots of
Gamma Irradiated Chicken Meat

	Negative Control No Chicken	Frozen Control Chicken Prod. 3 Lot 29	Gamma Irradiated Chicken Prod. 3 Lot 7	Gamma Irradiated Chicken Prod. 2 Lot 9
No. of CS Parents				
Female	15	15	15	15
Male	10	10	10	10
No. Days to Maturity	10	11	12	12
No. Parents Dead after 7 Days				
Culture #1	3	13	11	4
Culture #2	1	5	12	11
Culture #3	1	0	0	13
Culture #4	5	1	11	5
Culture #5	0	11	7	4
Total	10	30	41	37
Percent Mortality	8.0	24.0	32.8	29.6
No. Offspring after 21 Days				
Culture #1	725	197	19	56
Culture #2	536	209	24	20
Culture #3	566	240	32	50
Culture #4	789	346	25	50
Culture #5	784	180	23	51
Total	3400	1172	123	227
Ave. No. Offspring/ Culture	680.0	234.4	24.6	45.4

TABLE 6a

Dose Response Test - Individual Cultures

	Neg. Control Concentration of Chicken GI	5% Frozen Control Chicken	25% Frozen Control Chicken	50% Frozen Control Chicken	5% Gamma Irradiated Chicken	25% Gamma Irradiated Chicken	37.5% Gamma Irradiated Chicken	50% Gamma Irradiated Chicken
No. of CS Parents								
Female	15	15	15	15	15	15	15	15
Male	10	10	10	10	10	10	10	10
No. Days to Motility	10	10	11	13	10	11	12	15
No. Parents Dead after 7 Days								
Culture #1	3	3	4	4	0	4	11	3
Culture #2	1	1	5	5	1	21	12	2
Culture #3	1	1	3	15	1	8	10	18
Culture #4	5	2	2	1	3	1	11	17
Culture #5	0	1	3	1	0	5	7	25
Total	10	8	17	26	5	39	41	65
Percent Mortality	8.0	6.4	13.6	20.8	4.0	31.2	32.8	52.0
No. Offspring after 21 Days								
Culture #1	725	894	370	422	588	36	19	8
Culture #2	536	650	367	474	506	18	24	14
Culture #3	566	447	326	117	378	111	32	11
Culture #4	789	617	533	428	378	88	25	1
Culture #5	784	469	558	392	642	41	23	9
Total	3400	3077	2154	1831	2492	294	123	43
Ave. No. Offspring/ Culture	680	615.4	430.8	366.6	498.4	58.8	24.6	8.6

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TABLE 6b

Dose Response Test - Summary

	Frozen Control Chicken Prod. 3A, Lot 29	Gamma Irradiated Chicken Prod. 3, Lot 7
Concentration of Chicken - 5% Wet Weight		
Parent Mortality (%)	6.4	4.0
No. Days to Maturity	10	10
Ave. No. Offspring/Culture	615.4	498.4
Concentration of Chicken - 25% Wet Weight		
Parent Mortality (%)	13.6	31.2
No. Days to Maturity	11	11
Ave. No. Offspring/Culture	430.8	58.8
Concentration of Chicken - 37.5% Wet Weight		
Parent Mortality (%)	Not	32.8
No. Days to Maturity	Tested	12
Ave. No. Offspring/Culture		24.6
Concentration of Chicken - 50% Wet Weight		
Parent Mortality (%)	20.8	52.0
No. Days to Maturity	13	15
Ave. No. Offspring/Culture	366.6	8.6

	Negative Control
Concentration of Chicken - 0%	
Parent Mortality(%)	8.0
No. Days to Maturity	10
Ave. No. Offspring/Culture	680

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Re: Docket #84F-0230, Irradiation in the Production, Processing, and Handling of Food

August 19, 1985

Dockets Management Branch (HFF-334)
Food and Drug Administration
Room 4-62, 5600 Fishers Lane
Rockville, MD 20857

Dear Sirs:

This is a request to extend the comment period for written comments on the FDA's rule to permit the irradiation of pork to control trichinella spiritalis. The thirty (30) day comment period offered to the general public for input on the irradiation proposal is too short and an extension is requested for the following reasons:

- The possible long-term hazards of irradiation of meats have not been adequately addressed by either the FDA or Radiation Technology, Inc. RTI's Food Additive Petition (4M 3789) states that "changes in DNA [from irradiation] will induce DNA repair mechanisms so many mutations will only be temporary." (page 2) This is misleading at best, as irradiation of foods stimulates production of hazardous chemicals such as aflatoxins and various free-radical compunds. Relying on DNA repair to counteract the effects of irradiation is fallacious. The addendum to this docket by Maury Silverman (Aug. 16, 1985) includes some basic science on the biological effects of free-radicals.

- Because Congress has been in recess during the majority of the comment period, it has not been possible to have sufficient debate and investigation of the consequences of irradiation of the nation's pork supply. Therefore, a two or three month extension would insure proper consideration of this proposal both by the public and Congress.

- Trichinosis is no longer a major health threat in the United States. Proper cooking will kill trichinella in pork. Therefore, the reason given to irradiate pork - to obstensibly kill trichinella - is not believable, especially in light of new tests that can determine if pork is so contaminated.

- Radiation Technology, Inc. is on the highly select list of companies known as Superfund hazardous waste sites. A company that maintains a toxic waste dump and has been fined by both the NRC and the state of New Jersey for violations of their operating permit should not be entrusted with the safety of our food (See enclosed.).

- Irradiation will involve the transportation of millions of curies of dangerous fission products on the nation's highways. An environmental impact statement should be filed on the risks of an accidental release of radioactivity into the enviroment or at the irradiation facility.

- The FDA's previous approval of irradiation of bacon was withdrawn in 1968 after an "examination of the raw data for the animal feeding studies showed major deficiencies in the way some of the experiments were designed and conducted." (Statement of Sanford Miller before the Committe on Agriculture, May 9, 1984, p.7) No new evidence for irradiation has been presented by R.T.I. to justify reintroducing irradiation.

- Finally, the Department of Agriculture should be involved in the process by which food irradiation is considered. Having the Department of Energy promote this technology will leave the impression with many members of the consuming public that the FDA has shirked its responsibility to protect our food in order to promote "Atoms for Peace" at a time the United States is engaged in a massive buildup of nuclear warheads. If the FDA seriously wishes to investigate the possible long term effects of the irradiation of foods, the first step is to place irradiation under the jurisdiction of those government bodies who are involved with the protection of our food and our health, not those agencies which build nuclear weapons.

In short, the FDA should investigate this issue with carefully controlled studies and not merely rubberstamp the desires of the weapons manufacturers to "use up" fission products created by the production of plutonium-239. A moratorium on food irradiation, involvement of the Department of Agriculture, and an extension of the comment period are necessary to insure both the interests of justice and safety.

Sincerely,

Mark Robinowitz
Assistant

MR:ww

Enclosures

cc: Clyde Takeguchi
FDA
200 C St., SW
Washington, DC 20204

CANAH

Coalition for Alternatives in Nutrition and Healthcare, Inc.

P.O. Box B-12 Richlandtown, PA 18955

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Testimony of Catherine J. Frompovich, Ph.D.
Before
A Review of HR696 by Mr. Morrison
Federal Food Irradiation Development & Control Act of 1985

November 18, 1985

Good day, Members of the Subcommittee and House of Representatives. My name is Catherine J. Frompovich, and I am President of the Coalition for Alternatives in Nutrition And Healthcare, Inc. (CANAH). I hold a Doctorate in Nutrition and Holistic Health Sciences from Columbia Pacific University. May I thank you for the opportunity to present comments in opposition to food irradiation.

The issue of primary concern to us is that of safety which involves the various aspects, phases, and techniques used in the food irradiation process together with contradicting or questionable information on research and testing.

The most serious question in my mind is: Will there be genetic mutations as a result of food irradiation? In a statement submitted by Radiation Technology, Inc., a petitioner to USDA/FDA for food irradiation licensing, the following information appears: "Mutations are an inevitable consequence of irradiating foods, yet the creation of new organisms and/or organisms with increased pathogenicity is not a probable event for the following three reasons:

(a)
(b)
(c) Changes in DNA will induce DNA repair mechanisms so many mutations will only be temporary (Ingram and Farkas 1977)."

My questions regarding Radiation Technology's above statement are:

1. How can one say DNA mutations will only be temporary?
2. Who is to say who will be subject to the mutations?
3. What right does private industry or anyone else have to reprogram DNA repair mechanisms?

The report from which I recite this statement is known as "Finding of No Significant Impact for Food Additive Petition #4 3789, submitted by Radiation Technology, Inc. which concerns the use of gamma irradiation to control trichinae and other helminths in pork. Send to DMB Docket No. 84F-0130." Approved date: Jan. 28, 1985. May I ask that this information be made part of the public hearings on record. #1

Can you please tell me why the FDA approved pork irradiation just 3 days before the new EPA guidelines would have required an environmental impact report?

Regarding the studies to support safety of food irradiation processing, my question is why only "5 studies appeared to support safety, and all the remaining 64 were determined to be deficient"? Originally 441 summarized studies were presented; of that 266 were accepted or accepted with reservation, 147 were rejected and 28 were not categorized - and only 5 appeared to support safety. This poses another question: How can food irradiation be deemed safe based upon such a minute number of accepted studies? This information appears in a Department of Health & Human Services Memorandum from Food Additives Evaluation Branch, HFF-156, dated April 9, 1982 for the subject: "Final Report of the Task Group for the Review of Toxicology Data on

(over)

on Irradiated Foods." May I ask that this information be made part of the public hearings on record. #2

Still another question: How can a petitioner for the irradiation process claim that labeling not be required? In a letter dated July 30, 1985 from Radiation Technology, Inc. to USDA - F.S.I.S., its President Martin Welt states: "Although, the FDA is required by current regulation to consider food irradiation an additive, I believe that the FSIS can do away with a 'carry-through' labeling requirement on the grounds that the 'additive' would only be considered incidental to the process and not of any substantive value." Pasteurization is required by law to be on a label and so should irradiation along with the number of rads used to irradiate the foods or any food component. May this information be made part of the record. #3

And, my final question: How come there are no food irradiation guidelines? In my letter of August 27, 1985 to Dr. Engel at USDA, I asked if there were guidelines for irradiation doses and rads similar to the manual on chemicals known as "Compound Evaluation and Analytical Capability Annual Residue Plan". Dr. Engel asked Dr. George Pauli of Division of Food and Color Additives, HFF-330, Center for Safety and Applied Nutrition, to answer my question which he did in his letter dated October 10, 1985. Dr. Pauli said: "We have no such guidelines". Why? If there are no food irradiation guidelines, how can the process possibly be approved?

In summation, I would like to request that much more impeccable research be done - at various levels before our government considers this process. In addition, I respectfully request the FDA to withdraw its present approvals on the foods already approved for the food irradiation process.

Asst. Professor Jonathan B. Ward, Jr., Ph.D., The University of Texas Medical Branch, Dept. of Preventive Medicine and Community Health, Division of Environmental Toxicology, stated in a letter dated January 3, 1985 to Frank Young, M.D., Commissioner of the FDA, "I want to comment on the data currently available regarding the possible harmful genetic effects of irradiated food." "I have examined a series of papers describing dominant lethal studies in rats or mice using various types of irradiated foods. The dominant lethal test detects germinally transmitted genetic effects which are usually thought to be due to mutations at the chromosone level." May I ask that this information be made part of the public hearing on record.#4

Kenneth L. Applegate and John R. Chipley of the Dept. of Poultry Science, The Ohio State University, 674 West Lane Avenue, Columbus, Ohio 43210 in their paper Increased Aflatoxin Production by Aspergillus Via Cobalt Irradiation indicate that exposure to toxinogenic A. flavis spores to specific gamma radiation levels will induce higher yields of aflatoxins per unit of time, while non-toxinogenic aspergille remain unaltered with respect to aflatoxin production.

In the American Journal of Clinical Nutrition, February 1975, pp.130-135, the Effects of feeding irradiated wheat to malnourished children indicated Children receiving freshly irradiated wheat developed polyploid cells and certain abnormal cells in increasing number as the duration of feeding increased and showed a gradual reversal to basal level of withdrawal of irradiated wheat. May I ask that this information be made part of the public hearing on record. #5

"The possible genetic hazards associated with the consumption of irradiated foods were shown in experiments with plants..." "Subsequently, other investigators reported deviations in chromosomal structure and function in plants as well as mammalian organisms after treatment with irradiated sugar solutions..." This research is reported in the Int. J. Radiat. Biol. 1982, Vol. 42, No. 5, 559-563 in the article Non-induction of dominant lethal mutations in mice fed gamma-irradiated glucose. May I ask that a copy of this report and information be made part of the public hearing on record. #6

(Attachments follow:)

TESTIMONY OF CATHERINE J FRONPOVICH Ph D Nov. 18, 1985

FINDING OF NO SIGNIFICANT IMPACT

FOR

Food Additive Petition 4M 3789, submitted by Radiation Technology, Inc., which concerns the use of gamma irradiation to control trichinae and other helminths in pork.

Sent to DMB Docket No. 84F-0230

The approval of this petition will not require the preparation of an Environmental Impact Statement.

Prepared by: _____ Date: 1/24/25
for Barbara J. Marks, Biologist
Environmental Impact Section

Approved by: _____ Date: 1/24/25
Buzz L. Hoffmann, Ph.D., Chief
Environmental Impact Section

FINDING OF NO SIGNIFICANT IMPACT

Food Additive Petition 4M3789 was submitted by Radiation Technology, Inc. (RTI). It concerns the use of gamma irradiation to control trichinae and other helminths in pork.

RTI submitted an Environmental Impact Analysis Report (EIAR) under 21 CFR 25.1(j). After reviewing the information contained in the EIAR and in supplemental sources, we have determined that the subject food additive will not significantly affect the quality of the human environment. Thus approval of gamma irradiation of pork will not require the preparation of an Environmental Impact Statement. The basis for this finding is discussed below.

1. RTI will be using either cobalt-60 or cesium-137 as the gamma source for irradiating pork. The cesium-137 now in use was recovered from other sources, encapsulated, and placed in storage in the 1950's (see Memorandum of Telephone Conversation between Richard Cunningham and Carolyn Osborne, January 7, 1985). Any future manufacture or encapsulation of cesium-137 would fall under the jurisdiction of the Department of Energy. The Nuclear Regulatory Commission (NRC) has regulatory jurisdiction over the current manufacturing and encapsulation of other radioisotopes in the United States (such as cobalt-60) and has concluded that these processes will not cause significant impacts (see Memorandum of Telephone Conversation between Richard Cunningham and Barbara Marks, December 24, 1984, and FR 49: 9376, 9378-9). However, cobalt-60 will most likely be imported from Canada (see Memorandum of Telephone Conversation between John Maddox and Carolyn Osborne, January 22, 1985), which would have jurisdiction over its manufacture and encapsulation.

2. RTI certifies that their three irradiation facilities are in compliance with NRC or NRC agreement State licenses. These licenses include provisions covering worker notification of hazards in the workplace (10 CFR 19), worker exposure to radiation (10 CFR 20), disposal of radioactive wastes (10 CFR 20), loss of radioactive materials (10 CFR 20), permissible quantities of radioactive materials on the premises, leakage of radioactive materials, and radioactive emissions.

3. The two dosimeters (ferrous sulfate/cupric sulfate solution and radiochromic dyed nylon) are the only chemical emissions identified as associated with the pork irradiation process. RTI estimates that a maximum of 1 (one) pound of the ferrous sulfate/cupric sulfate solution per irradiator facility per year will be used. After its use this solution is neutralized and evaporated in accordance with Environmental Protection Agency-approved procedures. At this rate of use, each irradiator facility should discard 10 to 20 grams of the resultant salts (sodium sulfate, cupric sulfate, cuprous sulfate, ferric sulfate and ferrous sulfate) annually as part of the facility's solid waste.

Radiochromic dyed nylon dosimeters are made from laminated plastic sheets coated or impregnated with either leuco-triphenylmethane dyes or other radiation sensitive dyes (McLaughlin, et al., 1982). Twenty-seven 1 (one) cm^2 pieces of this material are used during each irradiation treatment. RTI estimates that 1,300 cm^2 of the material will be used annually per plant. Radiochromic dyed nylon is disposed of with other nonhazardous solid wastes.

Because of the low level of use of the dosimetry materials, the amounts of these substances entering the environment at solid waste disposal sites will be extremely small. Consequently, we do not expect any environmental impacts to result from these releases.

4. Radiolytic products (RPs) formed by irradiation become constituents of the food. The Division of Chemistry and Physics (DCH) has determined that only low concentrations of RPs are formed in pork irradiated at doses of 30 to 100 Krads, and that these levels of RPs are not a matter for concern in this instance (DCH memorandum of August 28, 1984). The Division of Toxicology (DT), relying on DCH's finding, also has concluded that the RPs formed at the proposed doses of radiation will not be a problem (DT memorandum of October 31, 1984).

RPs enter the environment through excretion following human consumption of irradiated pork. Because of the low levels of RPs formed in irradiated pork, we expect extremely low levels of RPs to enter the environment (environmental levels will probably be undetectable). Based on the expected level of environmental introduction and on the findings of both DCH and DT, we conclude that RPs will not have an impact on the environment.

5. Mutations are an inevitable consequence of irradiating foods, yet the creation of new organisms and/or organisms with increased pathogenicity is not a probable event for the following three reasons:

a) most mutations will be deleterious and will make the mutated organism less fit to survive in the environment;

b) there is no selection for mutated organisms over nonmutated organisms; and

c) changes in DNA will induce DNA repair mechanisms so many mutations will only be temporary (Ingram and Farkas, 1977).

In a review of the scientific literature concerning food irradiation, Mossel (1983) could not find any reports of increased pathogenicity of microbes due to single doses of irradiation, loss of determinative traits above the species level, or changes in the microbial communities which allowed pathogens to proliferate beyond what would occur with other processes used to treat food.

Ingram, M. and J. Farkes. 1977. Microbiology of Food Pasteurized by Ionizing Radiation. Acta Alimentaria 6(2): 123-185.

McLaughlin, W.L., R.D. Jarret, T.A. Olejnik. 1982. Dosimetry. In: E.S. Josephson and M.S. Peterson, Eds. Preservation of Food by Ionizing Radiation CRC Press, Inc., Boca Raton, Florida. pp 202-204.

Mossel, D.A.A. 1983. The Microbiogical Safety of Irradiated Food. Annex C: Health Hazards of Microbiological Nature Inherent of Foods Irradiated at a Level of Below 10KGy. Codex Alimentarius Commission. FAO/WHO CX/FH 83/9.

TESTIMONY OF CATHERINE J FROMPOVICH Ph D Nov. 18, 1985 Catherine TOR

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Memorandum

Date April 9, 1982

From Food Additives Evaluation Branch, HFF-156

Subject Final Report of the Task Group for the Review of Toxicology Data on Irradiated Foods

To W. Gary Flamm, Ph.D.
Acting Assoc. Director for Regulatory Affairs (HFF-752)
Through: Chief,
Food Additives Evaluation Branch (HFF-156) 4/23/82

At your request, we undertook the task of compiling and summarizing the toxicology data pertaining to irradiated foods. Our major objectives in this effort were to identify any consistencies and/or adverse findings, look for patterns, or trends in response between studies, and summarize the experimental results at the end of the review. These tasks were completed as of March 25, 1982.

The data review proceeded in three phases. In the initial phase, all relevant toxicology studies were identified from computer printouts, SIREN searches of our files, and review papers. In the second phase, the obtainable toxicology studies were summarized on "short" summary forms. Four-hundred-forty-one short forms were completed. This number is somewhat lower than the original estimate of 800 studies because of the many duplications in the papers, reports and documents available, unavailability of reports from the open literature, and unsuitability of some studies for review. Of the 441 summarized studies, 266 were "accepted" or "accepted with reservation," 147 were "rejected" and 28 were not categorized because they were general reviews. Studies were "rejected" if any of the following data were missing or insufficient for meaningful interpretation:

1. Irradiation dose not reported,
2. Irradiation dose less than 10 krad or more than 10 Mrad,
3. Group size not reported,
4. Group size for rodents less than 5, for days less than 4,
5. Inadequate diet,
6. No non-irradiated diet controls,
7. Administration other than oral,
8. Type of food not reported, and
9. Studies done by IBT.

Studies were "accepted with reservation" if the testing, on initial summary review, appeared acceptable but had some serious deficiencies interfering with interpretation of the data other than the "reject" criteria mentioned above. Studies were "accepted" if on initial examination they appeared to be reasonably complete.

In the third phase, all studies that appeared to show adverse effects and studies that appeared to support safety were then examined in detail on the "long" summary forms. Thirty-two studies indicating adverse results and 37 studies that appeared to support safety were examined in this phase. On detailed examination of these 69 studies, 5 studies appeared to support safety, and all the remaining 64 were determined to be deficient. The deficiencies in these studies fell into two categories, 1) problems associated with diet, and 2) inadequate experimental design. Some examples of these categories are presented below:

1 DIETARY PROBLEMS
- a. General dietary, vitamin, mineral and/or protein deficiency,
- b. Restricted food intake,,
- c. Unpalatable diet, eg. increased peroxidation of oils.

2. INADEQUATE EXPERIMENTAL DESIGN
- a. Inadequate control diet,
- b. "Replicate" experiments,
- c. Too few animals/sex/group, use of one sex, or numbers of animals were not reported,
- d. Combining data such as "total tumors," which is currently considered inappropriate,
- e. Inadequate presentation of the final report, or insufficient data for evaluation, e.g., only a summary was presented,
- f. Addition of anticxidants such as BHT or ethoxyquin added to diet either before or after irradiation,
- g. Insufficient recovery time for female animals between breedings in a reproduction study,
- h. Lack of random selection of groups,
- i. Questionable culling practices in reproduction studies,
- j. Inadequate histopathology,
- k. Animals too old for breeding purposes,
- l. Addition of extra animals in the middle of experiments, and,
- m. Inadequate length of time for a study, eg., carcinogenicity

Based on our extensive review of the data, we conclude that studies with irradiated foods do not appear to show adverse toxicological effects. The lack of effects however could have resulted from the dietary problems, inadequacies of experimental design, ambiguity and non-reproducibility of the available data on irradiated foods. Studies of sufficiently high quality to support the safety of irradiated foods treated at high irradiation doses which constitute major contributions

to the daily diet for long-term use are also not available. However, traditional toxicology (eg. subchronic or chronic) studies may not provide meaningful answers to safety questions regarding these types of irradiated foods. There are two major reasons for this situation. First, nutritional imbalances in the animal's diet due to feeding high levels of irradiated or non-irradiated foods would tend to mask any potential toxicological manifestations. Secondly, the extreme dilution of the potentially toxic unique radiolytic products in proportion to the high levels of irradiated foods themselves, would result in an inability, as in traditional toxicology testing, to exaggerate the dose of the test compound. For these reasons it would be difficult to devise a traditional toxicology study of sufficient sensitivity to provide assurances of safety for the population exposed to unique radiolytic products from irradiated foods constituting a major portion of the total diet.

The Irradiated Foods Committee in its July, 1980 final report, provided calculations based, in part, on considerations of radiation chemistry and physics that indicate that irradiation doses of 100 krad or less yield a limited concentration of total radiolytic products in food (30 mg/kg of radiolytic products, or 3 mg/kg unique radiolytic products). At such levels it would be difficult to detect and subsequently measure potential toxicological properties. If these unique radiolytic products are then considered in relationship to the total daily diet of a given population, the dilution of these radiolytic products becomes even greater. We therefore agree with the Committee's conclusion that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption and should be exempt from any toxicology testing requirements.

The completion of the administrative file including all "short" and "long" summary forms, a typed bibliography and all loose reports and published literature in our possession is ongoing, and will be transmitted as soon as it is finished to Dr. Takeguchi of Petitions Control Branch (HFF-334) along with a cover memo explaining in detail our review process.

M. van Gemert, Ph.D. Chairman

A. Trausquin, Ph.D. 4/23/82

J. Khalsa, Ph.D. 4/22/82 (with comments)

F. Lin, Ph.D.

V. Dunkel, Ph.D.

C. Sheu, Ph.D.

cc: HFF-156 (Kokoski, Morgenroth, Bleiberg, Hattan, Misra, Khalsa, Trausquin, F. Lin)
HFF-102 (Dunkel, Sheu), HFF-334 (Takeguchi), HFF-152 (Flamm, Edwards), HFF-100

TELEX: 642948 RNDH
ATTN: RAD TECH

Radiation Technology, Inc.

108 LAKE DENMARK ROAD, ROCKAWAY, N J 07866
(201) 625-8400

July 30, 1985

Dr. R. E Engel
Deputy Administrator
USDA - F.S.I.S.
Science
Room 402-Annex Bldg.
1-th Street and Independence Avenue, SW
Washington, DC 20250

Dear Dr. Engel:

We had hoped that by now the FSIS inspection of at least one of our irradiation facilities would have been completed. We had received a call from the USDA inspector in Raleigh, N.C. who had inquired when we expected to get the FDA approval for irradiating pork products since one of the pork processors he inspects has a trichinae problem.

Radiation Technology, Inc. which has received the FDA approval now seeks any USDA/FSIS approvals that may be required for the routine processing of fresh pork products or hog carcasses.

As previously explained to you, the Quality Assurance Manual submitted to your office describes in great detail all of the procedures utilized by Radiation Technology, Inc. to insure that all products received for irradiation while in our Care, Custody, and Control is processed in accordance with established protocols and with all records and processing information available for audit. Contrary to our earlier information, we expect to process boxed fresh pork products rather than exposed hog carcasses. Our Arkansas, North Carolina and New Jersey plants are capable of processing up to 2300 lbs. of fresh pork products per minute. Pallet loads are utilized in Arkansas and North Carolina whereas the Rockaway, New Jersey facility would require loading the cartons into metal totes prior to entering the irradiation chamber.

Radiation Technology, Inc. does not believe that the "food irradiation process" should be treated as an additive and hence requests that the FSIS do not require labeling of the processed fresh pork since to do otherwise would imply to some an additive has been imparted to the fresh meat as part of the food irradiation process; which obviously is not the case and may in fact mislead the consumer. Although, the FDA is required by current regulation to consider food irradiation an additive, I believe that the FSIS can do away with a "carry-through" labeling requirement on the grounds that the "additive" would only be considered incidental to the process and not of any substantive value.

RECEIVED

Radiation Technology, Inc.

Dr. R. E. Engel
Washington, DC 20250

We have received numerous inquiries from the fresh pork industry as well as supermarket chains wishing to proceed with production of "trichinae safe" pork products.

We would appreciate a prompt reply to the above rulemaking request together with the necessary plant inspections so that all industry uncertainty as to proper procedures for the irradiation of fresh pork in accordance with FDA regulations be initiated immediately.

We look forward to continued cooperation.

Sincerely,

Martin A. Welt, Ph.D.
President

MAW:jk

Enclosure

INSTITUTE OF CANCER PREVENTION D.C. Nov. 18, 1985

THE UNIVERSITY OF TEXAS MEDICAL BRANCH
GALVESTON, TEXAS 77550

Department of Preventive Medicine and Community Health
Division of Environmental Toxicology
Phone 409-761-1603

January 3, 1985

Frank Young, M.D.
Commissioner
Food and Drug Administration
Washington, D.C. 20204

Dear Dr. Young:

The use of gamma or electron beam radiation to sterilize foods has been under investigation for a number of years. I understand that the the FDA is in the process of establishing regulations for the use of radiation in food preservation. I want to comment on the data currently available regarding the possible harmful genetic effects of irradiated food.

Studies have indicated that simple solutions of sugars or nucleosides could be made mutagenic or clastogenic by gamma radiation (e. g. 1, 12). While studies like this raise questions about the safety of irradiated foods they are not helpful in assessing human risk from typical human diets.

I have [illegible] a series of [illegible] dominant lethal studies in rats or mice using various types of irradiated foods. The dominant lethal test detects germinally transmitted genetic effects which are usually thought to be due to mutations at the chromosome level. The test is not very sensitive but is thought to be specific when carefully conducted. Because intact animals are used the significance of positive results in determining human risk is much greater than the significance of in vitro mutagenicity tests. Of ten studies published between 1970 and 1981, three reported dominant lethal effects (6, 10, 11). The remaining seven studies failed to detect dominant lethal effects (2-5,7-9). Two of the positive studies reported post implantation deaths while one reported an increase in pre-implantation lethality (6). Only one of the ten studies included a positive control treatment (7), and it failed to produce the expected result. One unique feature of the positive studies by Vijayalaxmi was that food was used within a short period of irradiation. In one study they showed that storage of the food led to a loss of activity (10). One other study specifically used freshly irradiated material (3) but did not observe dominant lethal effects. The other studies either failed to indicate the time interval between food irradiation and use, or indicated that a period of several weeks elapsed.

In my opinion, these studies as a group fail to either prove or disprove the existence of a hazard from the use of irradiated food. It appears possible that unstable mutagenic products may be produced in foods by irradiation. If

transient products are generated by radiation the time of storage of a commercial product might have a significant bearing on its safety. Also, it is likely that the types of radioproducts formed in food would depend on the composition of the food. It is difficult to believe that that adequate tests of the effects of radiation on food can be conducted without individually evaluating the components of the foods for which radiation sterilization is intended.

I would encourage the FDA to carefully evaluate the existing data to determine whether it is adequate to conclude that food irradiation is a safe procedure. The dominant lethal test data is probably the most extensive available for the purpose of making a risk assessment. I do not believe that it is an adequate base for concluding that radiation sterilization has been shown to be safe. While radiation sterilization may ultimately be proven a safe and efficient method for food preservation the FDA would be failing the public by approving these methods before their safety is adequately established by well designed and carefully conducted studies.

Sincerely yours,

Jonathan B. Ward Jr., Ph. D.
Assistant Professor

JBW/tml
Enclosure

cc: Dr. Sidney Wolff

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✓ Dominant lethal effects demonstrated.

TESTING OF CATHEPSIN D PROMOTION FND Vol. 18, 1985

Effects of feeding irradiated wheat to malnourished children[1]

C. Bhaskaram,[2] M.D., and G. Sadasivan,[3] M.Sc., M.B., B.S., M.Sc.

ABSTRACT Fifteen children suffering from severe protein-calorie malnutrition were divided into three groups of five each and received diets containing either unirradiated, freshly irradiated, or stored irradiated wheat. All the children were hospitalized for a period of 6 weeks and leukocyte cultures were done initially and at intervals of 2 weeks. Children given freshly irradiated wheat developed polyploid cells and certain abnormal cells in their [illegible] the duration of feeding increased and showed a gradual reversal to basal level on withdrawal of irradiated wheat. In marked contrast, none of the children fed unirradiated developed any abnormal cells while children fed stored irradiated wheat showed polyploidy and other cells in significantly increased numbers. Though the [illegible] paralleled [illegible] with [illegible] the wholesomeness of irradiated wheat for human consumption [illegible]
J Clin Nutr 24: 130–135, 1975.

Irradiation has been recommended as a method to control insect infestation of stored grains, also to control sprouting in stored potatoes and onions. Irradiated foods have been screened for their wholesomeness and based on available evidence a Joint FAO/IAEA/WHO Expert Committee that met in 1969 to discuss this question recommended that "temporary clearance" may be considered in the case of irradiated wheat [1]. The Committee, however, specifically recommended that further studies for possible mutagenicity of irradiated foods should be undertaken, since in most studies done so far, tests for cytotoxicity of irradiated foods had not been employed.

While the wholesomeness of irradiated wheat has been studied extensively in experimental animals, similar studies in man are few and even these have been of short duration. Also, most studies have been carried out in well-nourished animals. In many developing countries, malnutrition is widely prevalent and there is evidence that malnutrition could adversely influence toxicity of many drugs. In such situations, the question of food irradiation thus acquires a new dimension.

In view of the large volume of literature generally supporting the absence of harmful effects of irradiated wheat in several mammalian species, it was thought that negative findings including cytotoxic studies in malnourished subjects [illegible] and that an attempt be made to [illegible] a method of increasing food availability.

An investigation was undertaken [illegible] to determine the effects of feeding [illegible] wheat to children suffering from [illegible] calorie malnutrition.

Materials and methods

Ten children aged between 2 and 5 years, suffering from kwashiorkor, were admitted to the hospital for investigation. All children had severe growth retardation, edema of the lower extremities, mental apathy and hypoalbuminemia—levels of serum albumin being below 2 g/100 ml. They conformed in all respects to descriptions of kwashiorkor given earlier from the Institute [2]. All children were rehabilitated with diets which provided 4 g protein/kg body weight and 120 kcal/kg body weight daily. These levels of protein and calories have been found to bring about optimal responses [3]. The diet contained 20 g wheat/kg body weight and provided about 2 g of protein/kg body weight. The diets of five children contained irradiated wheat, while that of the other five contained unirradiated wheat. Both groups of children were fed simultaneously. All the wheat used in these studies came from the same bulk supply. The rest of the protein in the diet came from dry skim milk. The children received these diets for a period of 6 weeks under supervision and it was ensured that [illegible]

[1] National Institute of Nutrition, Indian Council of Medical Research, Hyderabad-500007, India. [2] Research Officer. [3] Visiting Professor.

...as complete. The details of the diet used in the study ...as presented in Table 1.

...ked of irradiation

A local variety of wheat was obtained in bulk and ...adiated periodically in aluminum containers (4 x 4 ... 8 in.) in lots of 1.25 kg. The containers were kept at a distance of 12.5 cm from a cobalt-60 source which had a flux of 75,000 rads/hour. A total dose of 75,000 rads was given in four equally divided doses, exposing each side of the container at a time. Absorption of radiation was checked by standard ferrous sulfate dosimetry. The irradiated wheat was incorporated into the diets within 3 weeks after being irradiated.

The response of the children to these diets was ...luated using both clinical and biochemical parame... Clinical response was assessed by the time taken ... disappearance of edema and the gain in weight ... edema had disappeared. The biochemical re... was assessed by the rate of regeneration of ...m albumin. Albumin levels were determined by ...-Kjeldahl method. In addition, both before ...duction of treatment and at intervals of 2 weeks ...after, samples of peripheral blood were obtained to determine the extent and nature of chromosomal aberrations, using lymphocyte cultures.

Lymphocytes were cultured by a modified micro-method described by Arakaki and Sparkes (4) using phytohemagglutinin (PHA) as the mitogen. All cultures were terminated at 72 hours following a 2-hour period of exposure to 0.1 ml of 2.5 mg/100 ml colchicine. Chromosomal preparations were made by splashing on a wet slide, and stained with Giemsa stain. Twenty-five well-spread metaphases were analyzed for structural abnormalities like gaps, breaks, and deletions. During the course of the examination of these slides some cells with more than the normal complement of chromosomes were seen in some preparations. Therefore, in all preparations, 100 consecutive spreads were examined for the presence of polyploid cells.

As soon as it became evident that the feeding of irradiated wheat was associated with the appearance of polyploid cells, it was considered possible that this may have been due to the fact that the irradiated wheat was incorporated into the diets within 2–3 weeks after irradiation. The study was, therefore, repeated in five children, who received identical diets, but where the wheat after irradiation was stored for a period of 12 weeks before it was fed.

...LE 1
...position of the diet[a]

Ingredient	Amount, g/kg body weight	Protein, g/kg body weight	kcal/kg body weight
...n milk powder	6	2	20
...t	20	2	70
...ar	8		30
...fied butter	8		70
Banana one per day			

[a] The diet provided 200 kcal and 4 g protein/kg per ...y.

Results

The results of the study are shown in Tables 2 and 3 and Figs. 1–4.

There were no differences between the three groups of children either in the clinical or the biochemical response. But in four of the five children who had received freshly irradiated wheat, varying numbers of polyploid cells were seen. They first appeared 4 weeks after the diets were started, the mean incidence at this

...BLE 2
...nical and biochemical response to treatment

	Unirradiated wheat	Freshly irradiated wheat	Stored irradiated wheat
...ial weight, kg	7.8 ± 0.684	7.48 ± 0.674	6.68 ± 0.520
...ain in weight			
...at the end of 4 weeks, kg	0.88 ± 0.162	0.92 ± 0.287	1.40 ± 0.179
...at the end of 6 weeks, kg	1.44 ± 0.286	1.88 ± 0.314	1.88 ± 0.102
...rum albumin, g/100 ml			
...tial	1.46 ± 0.085	1.19 ± 0.097	1.45 ± 0.261
...um at the end of 4 weeks	1.12 ± 0.188	1.46 ± 0.401	1.14 ± 2.102
...um at the end of 6 weeks	1.37 ± 0.227	1.96 ± 0.216	1.66 ± 0.129
...moglobin, g/100 ml			
...tial	9.5 ± 0.95	10.5 ± 0.79	8.2 ± 0.77
...at the end of 6 weeks	9.5 ± 0.82	10.9 ± 0.62	9.6 ± 0.86

All values are mean ± SE. There are no differences between the three groups in any of the parameters studied.

time being 0.8%. At 6 weeks it had increased to 1.8%. In addition to distinct polyploid cells, where the number of chromosomes could be easily counted, there were other abnormal cells, characterized by splitting of their centromeres with widely separated chromatids. When these cells were also considered, the mean incidence of total abnormal cells at 4 and 6 weeks of feeding were 1.2 and 3.8%, respectively. In marked contrast, not a single polyploid cell or any other type of abnormal cell was found in any of the children who received unirradiated wheat. In the two children who were followed up after withdrawal of the irradiated wheat, the number of polyploid and abnormal cells had decreased considerably at the end of 16 weeks and by the 24th week all abnormal cells had completely disappeared. In children who had received the stored irradiated wheat, the incidence of definite polyploid cells was 0% at 4

TABLE 3
Incidence of polyploid cells in children suffering from kwashiorkor treated with unirradiated and irradiated wheat diets

	Unirradiated wheat	Freshly irradiated wheat	Stored irradiated wheat[a]
Initial	0	0	0
2 weeks	0	0 (0.4)	0
4 weeks	0	0.8 (1.2)	0 (1.6)
6 weeks	0	1.8 (3.8)	0.8 (0.8)

Figures in parentheses indicate the percentage of total abnormal cells, including polyploid cells. Consecutive cells from each child were examined at each time interval. Five children were studied in each group. [a] Wheat was stored for 12 weeks after irradiation prior to being fed.

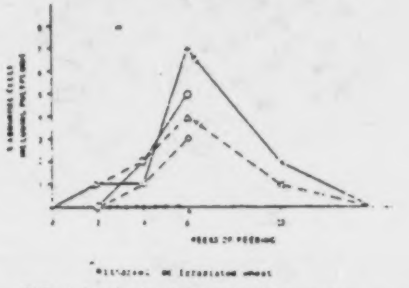

FIG. 1. Incidence of abnormal lymphocytes in children fed freshly irradiated wheat.

FIG. 2. Fuzzy chromosomal spread at the height of the disease.

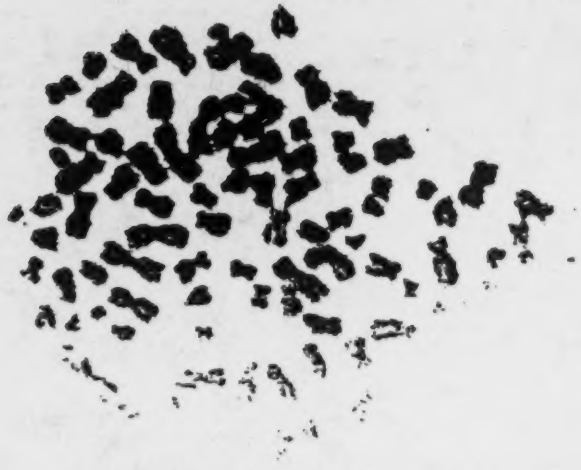

FIG. 3. Diploid cell in a child fed irradiated wheat.

FIG. 4. Abnormal spread in a child fed irradiated wheat.

weeks and only 0.6% at 6 weeks—figures considerably lower than those seen in children fed freshly irradiated wheat. Even when the other types of abnormal cells were taken into consideration, at 4 weeks and 6 weeks, the figures were 0.6% and 0.8%. This reduction in the incidence was found to be statistically significant ($P < 0.01$). In none of the 15 children studied was there a single polyploid cell at the time of admission.

There were no differences between the three groups of children with regard to chromosomal aberrations like breaks, gaps, and deletions. The incidence of these aberrations at the height of the disease and after treatment were essentially similar. At the height of the disease in all children, the chromosomal spreads had a fuzzy appearance with indistinct borders. With the institution of treatment and improvement in nutritional status, the chromosomal outlines became sharper and the fuzziness tended to disappear.

Discussion

The most significant finding in this study is the appearance of a number of polyploid cells in children who had received freshly irradiated wheat, none in those who had received unirradiated wheat, and a considerably reduced number of polyploids in those who had received stored irradiated wheat. It must also be considered significant that the number of polyploid cells progressively increased with increasing duration of feeding irradiated wheat and that these cells gradually disappeared after irradiated wheat was withdrawn from the diet. These observations clearly indicate that the appearance of polyploid cells is due to the feeding of irradiated wheat. They further show that storage of wheat after irradiation greatly reduces the cytotoxicity induced by irradiation. Though the mechanism by which irradiated wheat induces polyploid cells is not known, these data suggest that a "colchicine-like" substance might have been formed in the wheat, as a result of irradiation, which tends to disappear with storage.

The precise biological significance of polyploidy is not known, but polyploid cells have been shown to occur in man in malignancy, after exposure to irradiation, during viral infections, and in senility (5).

The long-term health hazard significance of polyploidy seen in the children studied who had received freshly irradiated wheat is not clear. On this will depend the answer to the question whether irradiated wheat is safe for human consumption. Though viral infections and administration of cytotoxic drugs may be associated with the presence of polyploid cells, its significance may perhaps not be the same as that of polyploid cells induced by the ingestion of irradiated wheat. While the former occur as isolated or as sporadic phenomena, wheat which is staple is consumed every day in large amounts and the consistent association of polyploidy with ingestion of such irradiated wheat has therefore to receive serious attention. The observation that polyploid cells were present in circulation 10–20 weeks after irradiated wheat was withdrawn acquires importance in this context.

Very recently, it has been reported from this Institute (Vijayalaxmi and Sadasivan, unpublished) that rats fed freshly irradiated wheat had increased numbers of polyploid cells in their bone marrows as compared with those fed unirradiated or stored irradiated wheat. A dominant lethal mutation effect, as well as reduced germ cell survival have also been reported in rats fed freshly irradiated wheat (8). In vitro cultures of human leukocytes in irradiated media have revealed significant chromosomal breakages (7). Viewed in the light of these observations, it is clear that a cautious approach has to be adopted to the whole question of the mutagenic potential of irradiated wheat.

The observation both in animals reported earlier from this Institute and in children reported here, that the cytotoxic effects of irradiated wheat were markedly reduced after it was stored for a period of 12 weeks must be considered important. They suggest that it is necessary to recommend that irradiated wheat be stored for periods beyond 12 weeks, before it can be considered safe for human consumption.

The authors are grateful to Dr. C. [illegible], Director-General, Indian Council of Medical Research, Dr. S. G. Srikantia, Deputy Director, Dr. N. Narasinga Rao and Dr. Vinodini Reddy, Assistant Directors, for their keen interest in this study and valuable guidance. They thank Dr. Sharat Chandra

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TESTIMONY OF CATHERINE J FROMFOVICH PhD Nov. 18, 1985 (#6)

INT. J. RADIAT. BIOL., 1982, VOL. 42, NO. 5, 559–563

SHORT COMMUNICATIONS

Non-induction of dominant lethal mutations in mice fed gamma-irradiated glucose

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1. Introduction

The application of ionizing radiation for the preservation of food and food components has come into recognition with the advent of nuclear technology. The possible genetic hazards associated with the consumption of irradiated foods were shown in experiments with plants (Natarajan and Swaminathan 1958, Swaminathan *et al.* 1962, Holsten *et al.* 1965), bacteria (Molin and Ehrenberg 1964, Dupuy and Usciati 1966), *Drosophila* (Chopra 1965, Rinehart and Ratty 1965, Schubert 1969) and mice (Moutschen-Dahmen *et al.* 1970. Kopylov *et al.* 1972). The genotoxicity of sugar solutions exposed to ionizing radiations was first reported by Ehrenberg (1960), who observed a high frequency of chlorophyll mutations in the M_2 generation of barley seeds exposed to irradiated glucose. Subsequently, other investigators reported deviations in chromosomal structure and function in plants as well as mammalian organisms after treatment with irradiated sugar solutions (Schubert 1969, Kesavan and Swaminathan 1971). Aiyar and Rao (1977) reported that irradiated sugar solutions were mutagenic towards *Salmonella typhimurium*, but non mutagenic in host-mediated assay with mice as the mammalian host. From the available literature it is not possible to arrive at conclusions with regard to the mutagenic risk to man from irradiated carbohydrates. The present investigation was undertaken to evaluate the mutagenicity of irradiated glucose by the dominant lethal test in male mice.

2. Materials and methods

D-glucose (anhydrous) obtained from M/s Sarabhai Chemicals, Baroda, India was used. Irradiation of glucose powder was carried out in polythene bags in the presence of air at room temperature (25 ± 1°C) using a ^{60}Co gamma source (Bhabha Atomic Research Centre, Bombay) at a dose rate of 56 to 58 Gy/min. The doses were measured by ferrous sulphate dosimetry. In all the experiments random-bred Swiss male mice were used.

2.1. *Experimental design*

Two series of experiments were conducted, namely short-term and long-term studies. In short-term studies, freshly irradiated glucose was used with 200 and 50 000 Gy dose levels while in the long-term studies, two sets of experiments were carried out with (i) freshly irradiated glucose (200, 2000, 20 000 and 50 000 Gy) and (ii) stored irradiated glucose (glucose was irradiated with 200, 2000, 20 000 and

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50 000 Gy and stored at room temperature for 2 months). In each experiment mice were randomly assigned to three groups as follows:

(*a*) Negative control group of mice fed on stock laboratory ration (Control 1).
(*b*) Control group of mice fed on unirradiated glucose in addition to stock ration (Control 2).
(*c*) Test groups of mice fed irradiated glucose (200, 2000, 20 000 or 50 000 Gy).

2.2 *Experimental procedure*

For the short-term studies, male mice aged 8–10 weeks were administered orally 2 ml of unirradiated/irradiated glucose (10 per cent) for 7 days. Following treatment each male was caged with two females of the same strain. The females were replaced by fresh females at weekly intervals. This sequential mating was continued for 8 weeks to establish the specific sensitivity during spermatogenesis (Oakberg and DiMinno 1960, Epstein *et al.* 1972). The females were sacrificed on the 16th day of presumptive mating and their uterine contents were examined for live and dead implantations.

In the long-term studies, two sets of experiments were conducted. In one set male mice aged 4–5 weeks were administered orally 2 ml of freshly irradiated glucose solution (10 per cent) continuously for 8 weeks. In another set of experiments male mice of 4–5 weeks of age were given orally 2 ml of stored irradiated glucose solution (10 per cent) continuously for 8 weeks. After treatment, each male was caged with two females of the same strain which were replaced at weekly intervals for 4 weeks. The pregnant females were sacrificed on the 16th day of presumptive mating and their uterine contents were examined for live and dead implantations. The dominant lethality was assessed in terms of pre- and post-implantation lethality. Pre-implantation lethality was determined on the basis of comparisons of total implantation rates between control and treated groups whereas post-implantation lethality was calculated in terms of per cent dead implants in relation to total implantations and also dead implants per pregnant female. The results were statistically analysed by applying square-root transformation on the dead implants per female for carrying out analysis of variance, and the '*t*-test' (Snedecor and Cocharan 1967). For total implantation rates, analysis of variance and '*Z*' tests were carried out. Further, the per cent dead implants over total implantations were statistically analysed using the Chi-square test of 2 × 2 contingency.

3. Results and discussion

Table 1 shows total implantation and survival rates with freshly irradiated glucose in the short-term studies. It is clear from the data that there were no significant differences in total implantation and survival rates between control and treated groups in any of the weeks representing both post-meiotic and meiotic stages of spermatogenesis.

The results obtained in the long-term studies with freshly irradiated glucose and stored irradiated glucose also revealed no variation in total implantation and survival rates between control and treated groups (table 2 and 3).

The data from the present investigation clearly indicate the inability of irradiated glucose to induce dominant lethal mutations either by short- or long-term feeding. These findings are in agreement with the observations of other investigators wherein irradiated sucrose failed to induce dominant lethal mutations in mice (Ivanc

Week	Control 1+2 Preg. fem.	TI	LE	Survival per cent (LE/TI)	200 Gy Preg. fem.	TI	LE	Survival per cent (LE/TI)	50000 Gy Preg. fem.	TI	LE	Survival per cent (LE/TI)
1	69	563	537	95·38	30	272	257	94·49	32	266	252	94·74
2	69	557	535	96·05	30	245	235	95·92	29	232	224	96·55
3	68	571	529	92·64	34	280	270	96·43	30	252	240	95·24
4	71	584	558	95·55	30	270	261	96·67	34	279	264	94·62
5	64	532	510	95·86	27	246	234	95·12	28	233	223	95·71

$P<0·05$; Preg. fem. = Pregnant female; TI = Total implants; LE = Live embryos.

Table 1. Total implantation and survival rates in female mice mated with males fed irradiated glucose (short-term studies).

Week	Control 1+2 Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	200 Gy Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	2000 Gy Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	20000 Gy Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	50000 Gy Preg. fem.	TI	LE	Survival (per cent) (LE/TI)
1	103	841	795	94·53	50	405	383	94·57	53	442	419	94·80	50	415	389	93·73	56	476	447	93·91
2	92	759	726	95·65	56	453	432	95·36	54	454	433	95·37	54	456	429	94·08	51	434	407	93·78
3	93	734	695	94·69	53	422	397	94·08	48	440	415	94·32	57	467	442	94·65	54	446	421	94·39
4	90	774	735	94·96	48	410	391	95·37	44	389	369	94·86	54	446	423	94·84	46	395	374	94·68

$P<0·05$; Preg. fem. = Pregnant female; TI = Total implants; LE = Live embryos.

Table 2. Total implantation and survival rates in female mice mated with males fed irradiated glucose (long-term studies).

Week	Control 1 + 2				200 Gy				2000 Gy				20 000 Gy				50 000 Gy			
	Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	Preg. fem.	TI	LE	Survival (per cent) (LE/TI)	Preg. fem.	TI	LE	Survival (per cent) (LE/TI)
1	94	580	537	92·50	46	384	363	94·53	54	446	428	95·98	33	286	268	93·70	50	414	388	93·71
2	91	772	732	94·82	40	333	312	93·69	51	413	395	95·64	39	326	306	93·87	48	406	380	93·60
3	90	723	687	95·02	43	360	336	93·33	54	450	420	93·33	33	274	259	94·53	44	356	336	94·58
4	86	750	709	94·53	38	315	303	96·19	42	338	317	93·79	28	230	217	94·35	39	329	309	93·92

$P < 0.05$; Preg. fem. = Pregnant female; TI = Total implants; LE = Live embryos.

Table 3. Total implantation and survival rates in female mice mated with males fed stored irradiated glucose (Long-term studies).

Committee on Atomic Energy, 1968) and chromosomal aberrations in rats and mice (Schubert 1969). The results of the present study are comparable with the absence of mutagenic effects of irradiated foods reported by others investigators (Aravindakshan *et al* 1975, Chauhan *et al*. 1975, Reddi *et al*. 1977).

On contrary, Aiyar and Rao (1977) reported a dose-dependent increase of reverse mutations in *Salmonella typhimurium* with irradiated sugar solutions. However, they failed to show any mutagenic effect with irradiated sugar solutions in the host-mediated assay with mice as the mammalian host. The absence of mutagenicity of irradiated sugar solutions in higher animals was presumed to be due to rapid detoxification and/or excretion of the radiolytic products of sugar solutions (De *et al*. 1969, Aiyar and Rao 1977). The absence of mutagenic effects of irradiated glucose observed in the present study may also be explained on the above lines.

It may be concluded from the results obtained in the present study that irradiated glucose is incapable of inducing dominant lethal mutations in mice. These observations are of considerable importance since it brings forth further evidence in support of the safety of irradiated foods for human consumption.

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Testimony of William J. Tromposch, Ph. D. - Dec. 18, 1985

Coalition for Alternatives in Nutrition and Healthcare
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PREPARATION AND PROCESSING OF FOOD ADDITIVE PETITIONS:
RADIATION APPLICATION TO FOOD

BUREAU OF SCIENCE STAFF SEMINAR
May, 1967

FOOD AND DRUG ADMINISTRATION
U.S. DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE / WASHINGTON , D.C. 20204

INTRODUCTION

The responsibilities of the Food and Drug Administration in the development of regulations involving applications of ionizing radiations to food are derived from the Food Additives Amendment to the Food, Drug, and Cosmetic Act. Radiation sources and radiation of food constitute special types of "food additives" as defined in the law. A food intentionally subjected to radiation is adulterated in violation of the Food, Drug, and Cosmetic Act, unless such irradiation is in accordance with a regulation established under the Food Additives Amendment.

ORGANIZATION OF PETITION PROCESSING

Bureau of Science

The Bureau of Science functions within FDA by making recommendations to the Commissioner on various regulatory matters. The recommendations are derived from conclusions on data supplied by petitioners and others, data available in the scientific literature, and data generated by the Bureau. Since FDA cannot generate all of the data itself, it must rely considerably upon data supplied by others. This is a major reason why the petitioner must supply the raw data derived from his experiments, in addition to the summaries and conclusions which he is entitled to draw from the data.

PETITIONS CONTROL BRANCH

The Petitions Control Branch (PCB) is primarily responsible for the management of FDA actions required by the Food Additives Amendment of 1958 (§ 409 of the Federal Food, Drug, and Cosmetic Act). Each Amendment establishes a similar means of providing for the use of food additives in or on our food.

The categories of petitions include: direct additives to food, packaging materials, and radiation.

The processing of food additive petitions involves the following considerations:

1. A new food additive must be evaluated for safety and regulated before it may be used legally.

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2. The proponent or petitioner of the substance must provide scientific data to support the necessary conclusion of safety for the regulation. The burden of proof is on the petitioner.

3. Safety of food additives is a relative, not an absolute, concept. It involves a practical certainty that injury will not result from the additive under the proposed conditions of use.

4. Before an additive can be approved, the petitioner must show it is effective. Because safety is relative, no more of the substance may be authorized than that which is reasonably necessary to accomplish the intended effect.

THE RADIATION PETITION

Before discussing the handling of the petitions, however, we must fully understand the meaning of the Commissioner's signature on an order enacting a regulation. The signature means that he has determined:

1. The use permitted is safe.

2. If a tolerance is required in the interest of safety, the amount permitted is no more than that reasonably necessary to accomplish the intended physical or other technical effect. (FDA believes that the effect shown should be related directly to the food use.)

3. The additive has not been shown to be a cancer producer. Or, it if it is to be added to animal feed, any carcinogen does not harm the animal, and there is no carryover into the edible products of the food-producing animal when the food is tested by an analytical method of adequate sensitivity, published in the regulation.

4. The regulation will not lead to deception of the consumer and will not lead to a violation of any other section of the Act.

DIVISION OF FOOD STANDARDS AND ADDITIVES

Extension of shelf life, for example, may be the end result of destroying surface spoilage organisms or of delaying maturation of a fruit. The presentation of the data should clearly delineate the actual degree of anti-mycotic or anti-bacterial effect and the effect on the maturity.

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More or less undesirable side effects may occur along with the desired effects from radiation. Additional work in nutrition, bacteriology, and radiation chemistry may be necessary to evaluate such factors as loss of vitamins, decreased digestability, induced radioactivity, and changes in the nature of the bacterial flora, etc.

Indirect additives bring up other considerations. For example, food contact surfaces may be irradiated; several such materials have already been regulated. The application of radiation is intended to produce its effect in the food and not in the food contact surface, but it may cause side effects in the package. Evidence showing no significant unacceptable effects must be shown. Will irradiation affect the food contact surface so that harmful amounts or types of migrants may become components of the food?

REVISION OF FOOD CHEMISTRY

The Additives and Instrumentation Branch is concerned with radiation petition data relating to the possibility of the production of induced radioactivity in the irradiated target, whether the target is the food intended to be processed or the packaging material only incidentally exposed. The Branch considers not only radiation produced by a nuclear transformation within the atom or molecule but also radiation produced when excited or metastable atoms return to their stable energy levels with the evolution of gamma photons.

This Branch also reviews the dosimetry information supplied in the petition, for accuracy and adequacy, and for induced chemical effects.

DIVISION OF MICROBIOLOGY

Radiation Processing

Proof of Effectiveness - 12D concept

Definition of 12D concept

The 4.5 Mrad dose would then be the 12 D value for Cl. botulinum. The required dose, calculated in this manner, is commonly called the "sterilizing dose" of radiation.

Possible Hazards

Although these hazards are remote, nevertheless, they must be considered.

a. An apparently sterilized product may contain damaged or attenuated organisms which upon long incubation under favorable conditions, may grow out. For example, an irradiated product tested for sterility

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(cont'd.)

a. following the U.S.P. procedure (incubation for 7 to 14 days in a suitable medium) showed no outgrowth; however, after 30 days incubation outgrowth did occur.

If sterility is not completely effective, the remaining organisms could be largely Clostridium botulinum. The destruction of the normal spoilage organisms by irradiation, leaving some Cl. botulinum, could obviously cause an extremely hazardous condition.

b. Resistent Mutents

If the intended sterilization is ineffective or incomplete, mutant strains of micro-organisms might appear. Organisms more resistant to irradiation may appear as a result of radiation-induced mutation. However, resistant forms would be likely to arise only as the result of repeated irradiation. Nevertheless, the development of radiation-resistant mutations might decrease the effectiveness of radiation processing.

Radiation Treatment

Hazards

a. As the result of the almost complete destruction of the natural vegetative micro-flora of a product by irradiation, the normal indices of spoilage (as the result of growth by these micro-organisms) may be absent and a spoiled product may not be recognized. Bacterial or fungal spoilage, such as taint or odor may fail to develop. Also, growth and toxin formation by such micro-organisms as non-proteolytic types of Cl. botulinum may result without the concomitant odor.

b. A second hazard of low dose irradiation is the possible development of resistant strains as a result of radiation-induced mutation. These progeny may be more resistant to subsequent irradiation than their parent strain. Although the increased resistance to irradiation can be induced only in certain strains of micro-organisms and can be accomplished only by repeated sub-lethal doses of irradiation, micro-organisms at the irradiation plant may become resistant to the lethal effects of radiation by the process of natural selection.

c. A third hazard is the destruction of natural inhibitors, permitting overgrowth by pathogenic organisms with greater resistance. This may be natural or acquired resistance. Because of the absence of competition from various natural micro-flora in the product, pathogens such as Cl. botulinum, which might have survived the irradiation process, may grow out very rapidly and with unusual proliferation.

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d. A third hazard is the destruction of natural inhibitors, permitting overgrowth by pathogenic organisms with greater resistance. This may be natural or acquired resistance. Because of the absence of competition from various natural micro-flora in the product, pathogens such as Cl. botulinum, which might have survived the irradiation process, may grow out very rapidly and with unusual proliferation.

e. If the spores of Cl. botulinum, which are more resistant to radiation than vegetative cell forms, are present in the product following radiation, the extension of shelf-life permits additional time for the pathogen to grow and produce its lethal toxin. An increased hazard of botulism will arise if storage of the product is not rigidly controlled. The times and temperatures of storage must be clearly specified and rigidly controlled to prevent the outgrowth of the organism as the shelf-life of the product is extended. The consumer must be made aware that low-dose irradiation does not result in a semiperishable product, and that the product must be treated as a perishable item.

f. Of particular concern to FDA is Cl. botulinum type E in fishery products.

(1) Recent surveys have shown that this organism is present in a great number of fish products. In certain geographical areas, from 50 to 80 percent of the fish may contain the type E organism. This is true, for example, of the fish from the Green Bay Area of the Great Lakes.

(2) The organism grows at relatively low temperatures. Outgrowth and toxin production can occur at 38° F. (33.3° C.) within 30 days. Under abuse conditions, obviously, the outgrowth time and toxin production would be quite rapid.

(3) Type E is also a nonproteolytic organism. Thus, the putrefactive odor usually associated with the outgrowth of Cl. botulinum types A and B in food would be absent.

(4) The requirements for anaerobiosis are not considered critical. The organism will grow out in most fish and fish products in an atmosphere. Thus, vacuum packaging or similar oxygen-free packaging is not essential for the outgrowth of the organism and the production of its toxin. The O-R potential of the fish flesh itself, is anaerobic enough for outgrowth of the organism.

DIVISION OF NUTRITION

Before seeking this answer, we must agree on what constitutes nutritional quality. The following should be included:

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a. vitamin content, stability, and physiological availability,

b. fat content, quality, and essential fatty acid composition,

c. protein quality,

d. digestibility of fat, carbohydrate, and protein components of a food, and the availability of the potential biological energy derived from them.

e. the absence of anti-metabolites,

f. the absence of toxic degradation products of radiation - sensitive nutrients and nutritional adjuncts (for example, carrageenin, starch, emulsifiers, artificial sweateners, EDTA), and

g. the subjective qualities of food that make it desirable to eat, such as color, flavor, texture, and masticatory and hunger satisfaction.

Although mineral content is, of course, an essential element of nutritional quality, it is not included in this context. The nutritional or metabolic utilization of minerals is not affected by irradiation, except through the possible induction of radioactivity.

Most of these seven factors could contribute to health risk. But from what is known about irradiation effects on these parameters so far, only vitamin content and stability, fat quality and essential fatty acid composition, protein quality, and the acceptability of the food have any real potential for harm in the nutritional area.

3. Petitions may include incomplete evaluations of the significance of experimental findings which signal a possible adverse effect. An example of this might be the raport of a finding or a significant increase in the liver cytechroma oxidase activity of male rats produced as a result of the consumption of an irradiated diet. How should the reviewer interpret such information in the absence of any discussion of its relationship to the safe use of the food in the human dietary? If it has no significance, it should either not be reported in the petition, or, if it is reported (the wiser course), it should be explained. For example, the petition could explain that such an effect is a normal one with unirradiated foods, and, therefore, within the area of normal biological variation in rats fed an uncomplicated ration.

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4. The question of alteration in biological availability is frequently unanswered though the possibility exists. There are no clear-cut methods to test this, and it is unreasonable to try to test this aspect in every petition on all nutrients. However, some experimental approach to a reasonable answer either through a microbiological assay for several vitamins or amino acids, or a feeding study using graded levels of a specific vitamin antagonist, could be sufficient. A complementary question concerns the effect of irradiation on subsequent stability of vitamins in the processed food. Do the data always show that nutritional value of the food at the point of maximum expected storage time is comparable to that of the thermally processed food at the same time? If it is reasonable to ask the question, it should be reasonable to expect an answer.

5. The results of animal feeding tests in which nutritionally complete rations are fed are sometimes cited as evidence that there has been no impairment in nutritional value of the irradiated food. The Division found an example of this fallacy in the report of feeding studies purportedly designed to test nutritional adaquacy of irradiated citrus fruit. Three experiments were on rats, for which vitamin C is not essential; two others were on monkeys who need vitamin C, but whose diets contained 65 percent ground Purina Monkey Chow which contains adequate vitamin C.

DIVISION OF TOXICOLOGICAL EVALUATION

Protocols

In general, acute studies are of little or no value in evaluating the safety of long-term ingestion of irradiated foods. Any toxic effects produced will be too subtle for detection in this manner except perhaps for certain blood and enzyme changes.

Subacute studies, too, offer little except for some value in comparison studies with a similar food which has had a chronic toxicity study.

Petition Evaluation

After DTE plodded through numerous articles in support of safety in one petition, it found that less than one-third of them were relevant to the food under consideration, and only three separate studies were involved. A few of the articles were merely dogmatic treatises on the problems of toxicology of irradiated food, but to read the conclusions based on actual experiments, one would have to conclude there were no problems.

However, in the case of irradiated foods DTE is concerned about the subtle, long-term, and perhaps cumulative effects. Short-term feeding to humans sheds little light on this question.

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DTE has noticed many instances of faulty presentation of toxicity data, including the following five:

1. In many instances, a very definite toxic effect was observed in some phase of the investigation, clearly associated with irradiation, and this was so stated. However, when the final evaluation of the study was summarized, this observation was somehow lost, and the conclusion stated that there were no toxic effects that could be associated with the irradiation.

2. In other instances an untoward effect was observed in the 2X level, but not the 1X level, or vice versa. But because there was not an effect at both levels the petitioner concluded that there was no relation to the irradiation!

3. DTE has noticed an effect occurring in the controls and in one irradiation level, but not in the other. The petitioner then concluded that because the controls had this effect too, it was of no significance.

4. In some cases there are many indications of poor animal performance, in controls and treated animals, and it is due to a pneumonitis in the colony or to some similar infections. In some instances there is no obvious reason, but there is simply poor performance in the case of the controls. No conclusions can be drawn from these studies that give any measure of confidence in the safety of the commodity. An experiment is only as good as its worst control.

5. A toxic effect has been observed in some phase of the experiment, and was noted as being clearly associated with the irradiation. Somehow through several reports and interpretations, the observation became less and less significant, until it disappeared. Ultimately the writer concluded that the irradiated food had been more beneficial for the animals than the control diet.

Many of these instances are related to the histopathological report. For example, much reliance is placed on the correlation of tumors in the control group with those in the irradiated group. If there are no statistically significant differences by the usual standards of P - 0.05, the petitioners concluded that there is no danger. However, where potential carcinogens are concerned, greater assurance than this is needed for human consumption.

Hence, every indication of a possible toxic effect associated with irradiation must be explored, regardless of its statistical significance in the collated data.

This also applies to auxiliary experiments, such as hemstology, ensymatic assays, etc. Questions have been raised in some instances by the results of such assays during feeding experiments, and these were clearly associated with the ingestion of irradiated food. The petitioners ignored them in the overall evaluation of safety, even when

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they mentioned in the report that the observations warranted further study. These have never been reexamined, or repeated as far as DTE can determine. Hence, a large question mark remains over the food in question until these observations have been thoroughly explored and their significance determined. Tests of this sort are relatively simple to perform, and in addition may shed some light on the effects of irradiated food that would not be observed with the usual observations of weight gain, etc., since they point to specific areas of attack. A follow-up of this work might lead to information which would explain some of the other toxic effects observed in the same feeding studies.

Another questions that has been raised in the past concerns the extrapolation of data from one food to another. Although this seems like a reasonable practice, at the present time there is insufficient knowledge of the effects of irradiation on individual foods to warrant such a practice. For example, one variety of fruit grown in two different parts of the country will behave differently under the influence of a given dose of radiation. The Bureau of Commercial Fisheries indicates that the same fish family, caught in different bodies of water, also will respond differently to irradiation. Lemons and oranges react differently toward irradiation. The composition in the first two examples are sufficiently different because of environmental conditions to cause different behavior to irradiation. It follows that the effects induced in the food are not necessarily the same, and also are not necessarily non-toxic. In view of these instances, extrapolation of data with some measure of confidence as to toxicological hazard is difficult at this time.

In many of the petitions submitted, the sections devoted to the effects and technical aspects of the irradiation far outweighed the sections attesting to safety.

Petitions Control Branch (PCB)

However, a statement that a fruit is "sound" may not be sufficient if, for example, the USDA classification does not include radiation pitting in its consideration.

ADDENDA: THE BIOMETHODOLOGICAL APPROACH

One of the first observations was made in 1948 by DaCosta and Levenson that peroxides in foods will destroy vitamin E. This seems like a rather simple observation, but many investigators who were testing irradiated foods on dogs or rats neglected it. Many problems of sterility arose. These experiments were conducted by some competent investigators in the United States. So, we must think about the role of vitamin E, and supplmeent the diet with vitamin E to be sure, we are not encountering nutritional artifacts. We must rule out nutrient effects when we are looking at frank toxicity.

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Concerning Clostridium botulinum toxin, for safety features the sterilization dose of 2 megarads had to be increased to 4.8. From this concept evolved the 6 megarad treatment dose representing the X and 2X dose. To insure that no toxin was present, impractically high doses were required.

Other problems which have been encountered include auricular repture in mice, reported by Monsen; "stored energy" reported by Ehrenberg; and the hemorrhagic diatheses effect involving vitamin K depletion.

Another problem reported by Sunminathan is the mutagenic effect observed in Drosphila raised on irradiated cereal products.

We must look critically and comparatively at all types of processing to see if we get any analogous effects.

We do not know yet what the compound in irradiated sucrose is that may produce the mutagenic effects. This we suspect is glyoxal. But what I am particularly interested in looking for here is how many and what types of peroxides we have. Are there any lactones that are produced, or do we have any 4-member or 5-member-strained rings which produce adverse biological effects.

If the investigators studying the toxic effects of aflatoxin had stopped at challenge periods of 3 or 4 months, they might have missed the very important finding on hepatomas as a result of aflatoxin stress. I do not think there is any argument that existing protocols are not satisfactory.

Protocols are now being adopted for mutugenicity. We need to look at several systems: cell culture, Drosophila, and others. Insofar as carcinogenicity is concerned, we must have an adequate number of animals surviving chronic experiments to establish tumor incidence. A pathologist observed that we sacrificed our animals too early in the Army program. He said that we did not have enough left to derive significant tumor data.

If you go up to 100 magarads, you can change a tree into digestible cellulose.

We must also look at the blood and urinary metabolites. I do not think we have used this approach enough, and could learn a lot from it. The metabolites of some of these products may be less innocuous or more innocuous than the original degradation products themselves. The nutritional problems are very important. A synthetic diet on which studies are based must be adequate insofar as the micronutrients and macronutrients are concerned. We must keep in mind that people do not eat basal rations. The diet that man eats is not analogous to experimental diets in the animal laboratory.

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NUTRITIONAL ADEQUACY

Many of the requirements for a petitioner to demonstrate the nutritional safety and adequacy of an irradiated food that were specified in the 1967 FDA document are still valid and, consequently, remain basically unchanged (see Appendex II, pp. 18-23) New "1980" criteria for the safety evaluation fo the nutritional adequacy of irradiated food, as contained in this section, essentially consist of a clarification or expansion of the 1967 document.

In the 1967 policy statement, nutritional quality was stated to include the following:

1. vitamin content, stability, and physiological availability,
2. fat contant, quality and essential fatty acid composition,
3. protein quality,
4. digestibility of fat, carbohydrate, and protein components of a food and the availability of the potential biological energy derived from them,
5. the absence of anti-metabolites,
6. the absence of toxic degradation products of radiation-sensitive nutrients and nutritional adjuncts (for example, carrageenan, starch, emulsifiers, artificial sweeteners, EDTA), and
7. the subjective qualities of food that make it desirable to eat, such as color, flavor, texture, and masticatory and hunger satification.

These continue to be regarded as appropriate factors for nutritional quality with a qualification that an assessment of the absence of the toxic degradation products of radiation-sensitive nutrients and food adjuncts is primarily a matter for toxicological rather than nutritional review.

From a number of studies on the radiation stability of vitamins, protein, fat and other nutrients, it is known that several nutrients are sensitive to ionizing radiation. This sensitivity, however, depends not only upon the nature and composition of the food system, but also on a number of controllable factors such as dose, temperature of the product being irradiated, and the relative presence or absence of oxygen in the product during irradiation.

Some of the macronutrient components - amino acids such as cystine, methionine and tryptophan, for example - are more sensitive to irradiation than others.

Even so, there is ample published evidence that a number of vitamins are labile to some degree when irradiated. Particular attention should be focused on vitamin A and carotene, vitamin E, vitamin C, vitamin B-12, thiamin, and vitamin B-6. Although other vitamins and essential nutrients must not be ignored, the aforementioned vitamins are noted because of published studies that demonstrate losses in irradiated products.

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To make this policy more explicit, restoration of a labile nutrient will be given consideration if the irradiation process has the potential to be highly advantageous for public health, economic, or other reasons such as the extended availability of seasonal or highly perishable products.

FACTOR III: IRRADIATION OF INDIVIDUAL DIETARY ITEMS

The Codex Alimentarius Commission will, in the near future, propose that dietary items representing 11 percent of the diet be approved for irradiation.

A worst-case estimate would predict that 40 percent of the human diet would consist of irradiated food (Table II plus Table III).

A program instituted by the government or private industry in an attempt to educate the public, with respect to the safety of irradiated foods, may encounter considerable resistance on the part of the consumer.

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TESTIMONY OF

THE UNITED FRESH FRUIT AND VEGETABLE ASSOCIATION

Before The

Subcommittee on Department Operations,
Research and Foreign Agriculture

Of The

Committee on Agriculture

U.S. House of Representatives

November 18, 1985

On Food Irradiation

Presented by:
J. Richard Graves, Jr.
Graves Brothers Packing Company
Wabasso, Florida

Chairman, Government Relations Committee
United Fresh Fruit and Vegetable Association
Alexandria, Virginia

Mr. Chairman, Members of the Subcommittee, I am Richard Graves of Graves Brothers Packing Company in Wabasso, Florida. We grow and ship citrus products both domestically and overseas under the name of Indian River Citrus Sales.

I also am the Chairman of the Government Relations Committee and past member of the Board of Directors of the United Fresh Fruit and Vegetable Association. United is the national trade association for the fresh produce industry. The 2,500 members include growers/shippers, wholesalers, retailers and affiliated industries from across the United States and twenty-one countries. United members handle eighty percent of the fresh produce commercially marketed in the United States.

On behalf of United, it is a pleasure for me to testify before the Subcommittee today on the issue of food irradiation. United fully supports the development and research of food irradiation as one possible alternative to some post-harvest treatments of fresh produce. Although not a panacea for treating all fresh produce commodities, irradiation does offer the possibility of improving the trade and marketing potential of fresh produce.

The produce industry has been severely hampered in meeting foreign quarantine regulations with the cancellation by the Environmental Protection Agency of Ethylene Dibromide (EDB), a post harvest fumigant used to disinfest certain commodities. Because of the cancellation of this important fumigant, the

produce industry is interested in the improved import and export potential irradiation offers to produce, in particular papaya, mangos, and apples, among others. Although the industry is also interested in irradiating citrus, further research and development is needed to determine the correct dosage without injuring the product.

In August 1985, United conducted a survey of a portion of the membership on the potential use of food irradiation by the fresh produce industry. Although all respondents agreed that food irradiation would eventually impact the produce industry, that impact will not be immediate. As one member responded, "After we, the public, become better informed, food irradiation will be a part of our every day lives, and the agricultural and produce industries will change radically."

There are still many hurdles to overcome before food irradiation will be commercially used by the fresh fruit and vegetable industry. Some of these are: achieving appropriate dose levels for disinfestation and marketability; economic viability; handling and distribution procedures; and the most important, the education of consumers and the food industry.

United has undertaken several activities over the past couple of years to help educate our members. Articles on food irradition have been published in our trade magazine, OUTLOOK; workshops on food irradiation have been held during our annual convention; and United has distributed white papers on food irradiation to the membership.

On the subject of the successful use of irradiation, United's survey respondents were primarily concerned about consumer acceptance of irradiated produce. Because of the necessity for consumer education on irradiation, United was one of the founding members of the Coalition for Food Irradiation. This coalition of food groups has been recognized as a credible source for information on irradiation and is conducting activities to inform the press, government officials and the general public.

I now would like to comment specifically on H.R. 696, the "Federal Food Irradiation Development and Control Act of 1985," introduced by Congressman Sid Morrison. United commends Mr. Morrison for taking the initiative in the U.S. Congress to bring this issue to the forefront. His interest and efforts have been a great asset in investigating the potential for food irradiation.

United supports the development of a "Joint Operating Commission" as described in H.R. 696. We must ensure that the federal government's research activities are coordinated to avoid duplication of efforts and to fill any holes. Although United does not wish to see the disruption of the important research activities of the Department of Energy, the U.S. Department of Agriculture must play a leading role in the development of food irradiation, since food irradiation is an agricultural issue.

United believes that the Joint Operating Commission will ensure that USDA has the resources, both informational and financial, to research food irradiation's affects on hundreds of products and to develop appropriate quarantine protocals. It is vital that all involved agencies cooperate and coordinate their activities to assist in this goal.

The Joint Operating Commission also is needed to assist in the education of the general public. Although the Coalition for Food Irradiation and other groups are already working toward this end, the federal government can play a vital role to complement and expand these efforts by educating not just consumers but also the agricultural industry.

The final and most important issue I wish to address today is that of labeling irradiated produce at the retail level. Although H.R. 696 changes the definition of food irradiation from an additive to a process, the bill retains FDA's authority to regulate it as an additive. That means that FDA has the authority to require mandatory labeling of irradiated produce at retail.

We realize that labeling is a very sensitive issue and has caused FDA to move slowly on finalizing regulations. Unlike freezing or canning, a person cannot tell if a commodity has been irradiated. The produce industry understands the interest on the part of some consumers who may want to know that their produce has been irradiated. Mandatory labeling, however, will

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not provide the necessary education about the process. Even though the food industry is undertaking programs to inform the general public about irradiation, there is a great concern in the produce industry that labeling will unnecessarily frighten consumers from purchasing irradiated produce.

There are several very practical problems that prohibit the accurate labeling of produce at the retail level, including the inherent quality of the perishability of produce, space limitations, misbranding, and enforcement. Because of its perishability, produce arrives at a retail establishment on a daily basis with several shipments arriving in any one day. The frequency of shipments makes it difficult to segregate loads in the back room. The increased consumer demand for fresh produce must be balanced by the amount of space in the produce department. The manager continually faces problems in utilizing limited space. He must constantly change displays depending on how much of a commodity is sold and how much is received.

Several suggestions have been made as to how irradiated produce may be labeled. One option offered is to place a sticker on each piece. Certainly there are machines which place stickers on such commodities as oranges, avocados, papaya or bananas. It is not feasible, however, to place stickers on individual mushrooms, brussel sprouts, asparagus stalks, and many other items.

Another suggestion is to place the shipping container with the appropriate labeling in view of the buyer. The amount of space that would be taken up by the shipping containers would severely limit the amount of produce that would be offered for sale, indirectly increasing the cost of the produce to the consumer. The less space available for produce, the less produce is sold. Retailers would need to increase prices to maintain profitability and would not be able to meet consumer demand for increased selection.

Placing signs or cards in the proximity of the irradiated commodity is a third suggestion. Because produce managers constantly change the arrangement of the produce department, it would be extremely difficult to ensure that the sign is in the correct space. This easily could lead to misbranding of the product. I am sure that many of you have looked for the price of an item in your local grocery store and it is sometimes difficult to locate. Maintaining pricing information in the produce department is a difficult task and exemplifies the burdens produce managers have with signing.

There are several potential misbranding dangers should produce be required to be labeled. Consumers purchase produce with their hands. They pick it up, feel it for ripeness, look for uniformity in color and in some cases smell it. If there are two bins of apples for example, one irradiated and one not irradiated, there is nothing to prevent the consumer from picking up an apple from the irradiated bin and mistakenly

putting it back down in the non-irradiated bin. The retail establishment could be held legally liable for misbranding even though control is completely out of their hands.

Another potential problem could exist with produce clerks unknowingly combining shipments of irradiated and non-irradiated products. Misbranding could occur in haste to maintain stock levels and in the confusion of shipments arriving thorughout the day.

For any law or regulation to be effective, it must be enforceable. Labeling of produce at the retail level is not enforceable. Although FDA regulates food additives, they must rely on state agencies to enforce those regulations at retail. Historically state agencies have been ineffective enforcement arms for the federal government because of a lack of manpower. Because of a lack of enforcement capability on the part of FDA, and the unfairness of putting retailers into situations where they cannot control possible misbranding, United urges that H.R. 696 be amended to exempt irradiated fruits and vegetables from mandatory labeling at retail.

Instead, United recommends that irradiated produce be regulated just like other produce which has received a post-harvest treatment by requiring labeling of the shipping containers. Under section 403(l) of the Food, Drug and Cosmetic Act, raw agricultural commodities which have been treated with a post harvest pesticide, "must have the shipping container of such

commodity bear labeling which declares the presence of such chemical in or on such commodity and the function of such chemical...."

United recommends that Section 3(c)(1)(D) of H.R. 696 be amended by inserting the following:

> (iii) adding after "and the reasons therefore" the additional sentence "Providing however, where irradiation is used on raw agricultural commodities in place of a post harvest pesticide any labeling regulations will be consistent with section 403(l) of the Food, Drug and Costmetic Act (21 USC 343(l)"; and

An inherent protection in labeling of the shipping containers will be prevention of re-irradiating the commodity, insuring that the produce has been treated within the safety limits established by the FDA. In addition, FDA and the appropriate state agencies will be able to enforce these regulations in the packing houses or irradiation facilities. United urges the Subcommittee to make this amendment to ensure enforceability of possible regulations.

Thank you again for inviting me to testify. I would be happy to answer any questions you may have.

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TESTIMONY SUBMITTED TO

SUBCOMMITTEE ON DEPARTMENT OPERATIONS,

RESEARCH, AND FOREIGN AGRICULTURE

OF THE COMMITTEE ON AGRICULTURE

OF THE HOUSE OF REPRESENTATIVES

NOVEMBER 18, 1985

PRESENTED BY

DR. C. D. VAN HOUWELING

NPPC STAFF CONSULTANT

The National Pork Producers Council (NPPC) appreciates this opportunity to appear and testify relative to our position on irradiation processing of food, specifically pork. The NPPC represents virtually all pork producers and their families nationwide. Our primary mission is to enhance the pork producers opportunity for a profit.

In 1982 NPPC delegates passed a resolution pledging an all-out effort to solve the problem of trichinosis in pork. Subsequently, a national task force was named. Several government, industry, and organizational representatives were named to serve. At their first meeting, they chose Trichina Safe Pork Task Force as their name, and as their goal, a 100 percent retail pork supply safe from the threat of human trichinosis by 1987.

It should be pointed out that currently trichinosis is not a huge public health issue. Only about one hundred cases are reported each year. Even though it is not a major public health problem, NPPC believes that the human suffering that does occur needs to be eliminated. The technology now exists to reduce the incidence of trichinosis from pork to zero.

The primary concern to NPPC, in addition to public health considerations, is consumer reaction to the entire issue of trichinosis. A percentage of the population does not eat pork because of the potential threat of the disease. Over 25 percent of the respondents in an NPPC survey said that they consume less pork because of the fear of trichinosis.

Almost 90 percent of respondents in consumer attitude surveys indicate that they know that you have to cook pork until it is well done and they consider this undesirable. Add to this the fact that the longer cooking at higher temperatures reduces the flavor of pork and thereby reduces its palatability. This is also confirmed by the response of 40 to 50 percent of the consumers surveyed who felt that pork is drier than other meats after cooking.

Admittedly, the actual impact of trichinosis on pork consumption is difficult to assess because conclusive evidence at this point is virtually impossible to obtain. The research figures just presented do suggest that the total elimination of this parasite in the pork supply might significantly increase pork consumption and therefore, the profitability of pork production.

NPPC's Trichina Safe Pork Task Force took the lead in identifying and developing methods in addition to irradiation which would result in a retail supply safe from trichina. Among the methods studied on were the pooled digestion tissue test and the ELISA serum test. There are regulations permitting the use of the tissue test as an official way to certify pork as trichina tested. NPPC is the process of preparing a petition requesting approval of the ELISA test as well.

The traditional methods for control of trichina in fresh pork are cooking, curing or processing, and freezing.

About the time that the NPPC Task Force started its work, U.S. Department of Energy (DOE) personnel approached NPPC to see if we had any interest in control of trichina in pork through the irradiation

process. It was noted that experimental work had already been conducted that proved irradiation of pork could render the trichina parasite sterile. This stimulated NPPC's interest in the irradiation method. Much research has taken place since then.

The USDOE, in cooperation with USDA, conducted studies which confirmed the efficacy of gamma radiation at a dose of 15 - 30 krads for the sterilization of Trichinella spiralis in pork. Studies using different cuts of infected pork showed that there is no variability in the radio-sensitivity of the trichina in different muscles. Irradiation is effective regardless of whether the whole carcass or ground pork are irradiated. The data clearly indicates that 30 krads of cesium-137 gamma radiation can be delivered to split carcasses of market weight hogs with acceptable uniformity, and that such a dose can provide a substantial margin of safety for human consumption.

It was recognized that there should be additional data in regard to the effect of even a low dose of radiation on palatability of pork. NPPC and the USDOE, in cooperation with Iowa State University, investigated the effects of 100 kilorads of irradiation on the micro flora, sensory characteristics, and the development of oxidative rancidity of vacuum packaged pork after irradiation and at low temperature storage for up to 21 days. As the increased storage progressed up to 21 days, the difference noted between the irradiated and non-irradiated pork became less, indicating the potential for increased beneficial effect of low doses of irradiation with longer holding of the product after treatment.

It is reassuring that these studies have shown that the irradiation of pork at the low level necessary to inactivate the trichina parasite does not affect the organoleptic characteristics or microbial populations adversely.

Dr. Ronald Engel, the head of science for the Food Safety Inspection Service (FSIS) said in a talk presented on October 29 in Milwaukee, Wisconsin, "All food processors cause changes in the chemical nature of food including home cooking. The major difference seems to be that food irradiation is not as comfortably familiar as are canning, freezing and curing". In his speech he also sought to dispel "many misconceptions" associated with food irradiation. He said "there is no justification for anxiety about these matters".

NPPC also cooperated with the USDOE on a major economic feasibility study involving irradiated pork. That study anticipated at least a two percent increase in domestic demand and fully a one-third increase in foreign demand for trichina-safe pork. These increased percentages translate into an almost one-half billion dollar return from having all pork trichina-safe during the first year alone.

Another study conducted by a staff economist at USDA's Economic Research Service placed the cost of trichinosis and toxoplasmosis from pork at between $216.5 and $325.2 million annually. Low dose irradiation of all pork in the U.S.should eliminate these national public health costs.

One of the major obstacles to food irradiation in the U.S. is the acceptance by consumers of the process. In an effort to determine

what knowledge consumers in the U.S. had about irradiation and how they regarded the procedure, NPPC, with the cooperation of the USDOE, conducted a national survey of consumers. The study showed that almost 40 percent of the respondents had a major concern for food irradiation. However, this figure needs to be put into some perspective. A greater number expressed a major concern for every one of the alternatives to food irradiation. Fifty-five percent of the respondents had a major concern for chemical sprays used on some fruits and vegetables that they eat; 50 percent expressed a major concern for the risk of becoming ill from diseases in or carried by food they eat; 43 percent were greatly concerned by preservatives that are being used in some of the foods they now eat; and 47 percent were concerned about the waste from having to throw away food they buy that spoils before they eat it. I am including for the record a copy of the NPPC publication Consuming Topics, volume 2, number 5, which reports in more detail the results of this survey.

The labeling issue was also addressed in the survey. NPPC is convinced that any irradiated product must be labeled. The reasons include: (1) the consumers right to know, and (2) the belief that irradiation provides a real value-added advantage for treated commodities. In order to realize this advantage, the product must be labeled so that the consumer can select or reject the irradiation processed product.

Beyond the issue irradiation is the question of labeling for trichina safety. As stated before the NPPC is in the process of developing a petition for the approval of the ELISA testing method. That petition will probably ask for a label indicating that the product has been

tested for trichina. For irradiated products, the label should convey the message that the product is trichina safe. Therefore, the suggestion has been made that the label utilize some distinctive logo indicating that the product is trichina safe without using the word "trichina." This could then be integrated into existing industry and government consumer education programs so that consumers would realize that they can enjoy the new pork without overcooking it.

Acceptance of this new irradiation technology by the U.S. pork packing industry will be based upon at least three factors. These include the trichina safe aspect, consumer acceptance of the technology, and the cost savings brought about by the elimination of the need to follow expensive, regulated processing procedures to render processed pork trichina safe.

NPPC would like to comment upon the proposed legislation HR 696. The legislation proposes to change consideration of irradiation from an additive to a process. We think that the proposal is constructive legislation, but our concern is that approval of the process might be as difficult as getting approval of a food additive. If this is the case, very little would probably be accomplished.

We do strongly agree that irradiation is a process and not a food additive. I would like to introduce for the record the summary from the Cast Publication "Is Radiation a Food Additive".[1] I would like to read a paragraph from this summary.

Irradiation of plants by the electro-magnetic radiation in the visible light range, plays an essential role in food production. Both plants

and animals, the sources of human food, receive radiation, not only in the visible range, but also in the infra-red and ultra-violet ranges.

Irradiation of food products by the electro-magnetic radiation produced by radio-active cobalt or cesium (gamma radiation) can be used to rid foods of bacteria and other micro-organisms that cause spoilage or disease as well as to disinfest foods of insects and other undesirable organisms.

The chemical changes produced in foods even by high sterlizing doses of gamma radiation are minor. The compounds produced either are identical with naturally occurring compounds in fresn foods or are produced in amounts smaller that those produced when foods are processed using conventional, well established methods such as cooking. In more than 25 years of studies with irradiated foods, no harmful effect has ever been identified as due to the irradiation of the foods.

The Food Additive Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act, defined radiation as a food additive. This definition has had various inhibitory effects on the use of food irradiation in the past and more are envisioned for the future. Radiation is a form of energy, not a material substance. Thus, radiation is not a food additive, and the definition is scientifically erroneous.

NPPC has a concern in regard to establishing the Joint Operating Commission for food irradiation. If consideration of irradiation issues by agencies would be deferred to the commission, or postponed because of the commission's responsibility in this area, the entire

program could be severely handicapped. Although, NPPC greatly commends the sponsors of this legislation for development of a solid research and consumer education approach to irradiation, we are somewhat concerned about the formation of a new bureaucracy that might serve to actually retard advancement in this important field that holds so much promise for the U.S. pork industry. It appears that the momentum building in this country to utilize the irradiation process may make this Commission obsolete before it gets established.

We are also concerned about including section 5 dealing with Leasing of Nuclear Byproduct Material for Food Irradiation legislation. We would also favor eliminating paragraphs 11, 12, 13 in Section 2 Finding and Purposes as well as Section 5. If there is a problem that needs to be addressed we would favor doing that with separate legislation.

NPPC sincerely appreciates the opportunity to present our views for consideration by this subcommittee.

Respectively submitted.

C D Van Houweling

Dr. C. D. Van Houweling

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(1) Council For Agricultural Science And Technology, Is Radiation A Food Additive - 1984-3 May 1984, Ames, Iowa. (ISSN01944096)

(Attachment follows:)

CONSUMER ATTITUDES ON FOOD IRRADIATION

Food irradiation is a subject that's much talked about these days. While it's long been utilized abroad, presently U.S. regulations do not allow its use for food other than spices, but all indications are that within just a few years irradiation will become a reality in this country as well.

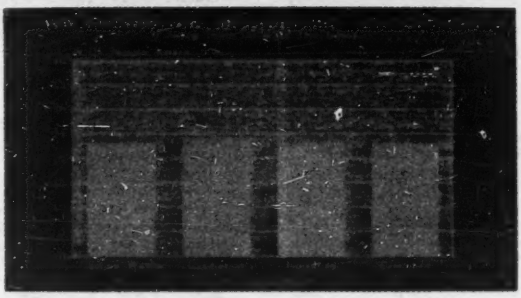
A growing number of industries are realizing the huge potential irradiation offers. The pork industry, for one, is optimistic about the process which, for the most part, involves sterilizing or preserving foods by killing certain organisms that may be present.

For pork, it enjoys not only the capacity for increasing consumer consumption and reducing the use of preservatives in various processed products, but, perhaps most important, guaranteeing no chance of ever contracting the disease known as trichinosis.

The widely held belief that trichinosis is a problem has long stigmatized the pork industry, even though in actual terms it is more a perceived problem than anything else. Today the chances of contracting it are almost nonexistent due to modern production practices. Still, there is no doubt many consumers invariably overcook pork, sometimes to the point of shoe leather toughness, simply because mother or grandmother always warned that pork, by nature, must be thoroughly cooked.

About 2 years ago the National Pork Producers Council decided the time was right and the technology — irradiation — was available to move toward certifying pork trichinae-safe, thus totally eliminating the possibility of ever contracting trichinosis from pork.

Since then, research indicates irradiation could bring about a 2 percent increase in domestic sales of pork and a one-third increase in exports resulting in $449 million to the industry the first year alone.



Consumer attitudes on food irradiation obviously are crucial to its acceptance. In a study which began in January, 1984, NPPC asked 1000 respondents of selected households nationwide questions to determine what they think about food irradiation.

Based on the question, do you eat a lot less, some less, or a little less of certain foods today because of certain reasons, the study found that 40 percent had reduced their consumption of pork because of salt, 33 percent because of nitrites, and 24 percent because of trichinosis.

Twenty percent had reduced their consumption of beef because of disease compared to 20 percent for fish and 16 percent for poultry.

In addition, while consumers are concerned about chemical sprays routinely used on fruits and vegetables, they generally have not reduced their consumption of these foods. Only 20 percent had reduced their consumption of fruits because of chemicals and 17 percent for vegetables.

Not surprisingly, the word irradiation raises some concern. One-third of the respondents were asked about each of three terms currently used to describe the process. Of the three — gamma waves, irradiation, and ionization — only 20 to 25 percent of them had ever heard of any of the terms prior to the interview. When asked about initial levels of concern for these methods, an average 40 percent had a major concern while 65 percent had a major or minor concern.

Moreover, consumers do not particularly favor the alternatives to irradiation. In fact, each of the alternatives had a greater level of major concern than did irradiation. Fifty-five percent of the respondents had a major personal concern for chemical sprays routinely used in fruits and vegetables compared to 52

percent for preservatives, 50 percent for food-borne disease, and 46 percent for food waste and spoilage. By comparison, only 39 to 40 percent had major personal concerns for irradiation.

Labeling of foods treated by irradiation is a major issue and has spawned considerable controversy among industry and government officials as well as consumers. For some, use of the word "irradiation" or "irradiated" tends to connote negativism.

When NPPC asked the respondents how often they actually read labels of foods purchased, 21 percent of them said all of the time compared to 33 percent most of the time, 30 percent occasionally, and 16 percent never read food labels.

What's more, the survey found that 50 percent of the respondents had a major concern for the word irradiation while 25 percent had a major concern for the word ionization. By and large, any conclusion that can be drawn is this: Labeling is highly important to consumers and there is no doubt it will figure decisively in the acceptance of irradiation. Because terminology is so debatable, it has been suggested by some that a symbol or mark of some sort be instituted on food packages as it would likely be more acceptable by consumers.

The process of irradiation involves the passage of gamma waves through food much as microwaves pass through food in a microwave oven. The food itself in no way becomes radioactive. And besides being used to sterilize and preserve foods and expand their shelf life, irradiation enjoys vast other attributes.

Foods retain their flavor, color, and nutritional value, and they likely will be considerably less expensive as they do not necessitate freezing and refrigeration. Further, cooking times are reduced. Like beef, pork could be cooked to an internal temperature of 140°F. (rare) compared to the 170°F. (well done) now recommended.

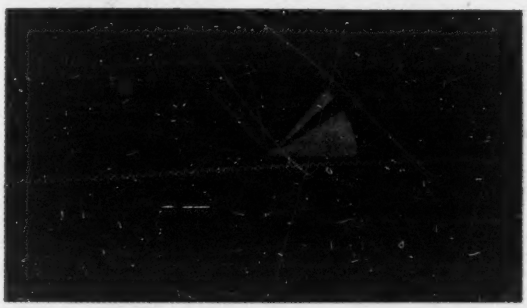
Irradiation will reduce or eliminate both the need for preservatives, such as nitrites in processed products, and chemicals in fruits and vegetables. Food losses because of spoilage will be reduced so irradiation has the potential for greatly diminishing world hunger. And this factor alone was far and away the most persuasive among survey respondents. Fully 35 percent of them support the use of irradiation to ease world hunger.

Given its other benefits, 12 percent support the process because of the fact that the Food and Drug Administration has already approved it for spices as well as a proposal for fruits and vegetables, 9 percent because it is currently used to sterilize medical and surgical products, 6 percent because it has successfully been used abroad for several years, and 6 percent because foods eaten by astronauts in space are irradiated.

But of these added benefits, the largest number of respondents — 23 percent — support irradiation because of the fact that it does not impart radioactivity in food.

NPPC's survey, the first of its kind on the subject of irradiation, clearly indicates consumers do have concerns, especially in regards to labeling. At the same time, many also recognize its virtues. Like other food preservation processes, certainly it can go a long way toward enhancing the safety and wholesomeness of food.

Until then, education by industry and government alike is essential for consumer acceptance and approval.



Testimony by
NATIONAL FOOD PROCESSORS ASSOCIATION
on
Food Irradiation
and H.R. 696
Before the
Subcommittee on Department Operations, Research
and Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives

Mr. Chairman and members of the committee, I am Lawrence T. Graham, Executive Vice President of Public Affairs, of the National Food Processors Association (NFPA) and I am pleased to have this opportunity to testify before your subcommittee regarding the potential for a new food processing technology, irradiation. NFPA is a scientifically and technically based trade association that represents nearly 600 companies including most of the major food processing companies in the United States. Our member companies pack processed fruits, vegetables, meats, fish and specialty products including canned, frozen, aseptic, dehydrated, pickled and other preserved food items. Included in our membership are companies that manufacture packaging and processing equipment, or provide supplies and services to the food processing industry.

This association's diverse membership and scientific background have made our interest almost automatic in the potential of irradiation either as one step in the processing of food or as "the" process before retail sale to the consumer. NFPA has always been in the forefront of technological development in food matters and irradiation is just another logical area to explore.

On February 14, 1984 FDA published a long awaited proposal on the use of radiation in the processing of food products. That proposal when final would permit low level irradiation of fresh fruits and vegetables. Such a process would inhibit sprouting and increase shelf life in fresh fruits and vegetables, would control insect infestation of products and would destroy microbial growth in spices and other seasonings. Manufacturers would be required to maintain process records and make the records available for FDA inspection.

The most controversial issue raised by the FDA proposal deals with labeling. The major concern of the food processing industry has been that any labeling of irradiated food products might be viewed by the consumer as a warning. This is another reason NFPA wishes to stress that the government as well as the food processing industry must develop programs to educate the consumer as to what irradiation really does and what the benefits are.

It is our understanding that FDA's final regulation will require that packaged fruits and vegetables include the statement "treated with radiation" on the label. Unpackaged fruits and vegetables will either have to have each piece labeled or the information displayed by labeling a bulk container or use of a counter sign stating the product has been treated with irradiation. These procedures are very similar to those now used when waxes or coatings have been applied and for processed foods sold in bulk without packaging.

Several groups have recommended that the United States allow use of the logo that already has become a recognized symbol

internationally. But FDA has said that use of the logo in this country would have to be used with the statement "treated with radiation" for at least two years in order to educate the general public.

FDA has already approved the use of irradiation to control Trichinella spiralis in pork carcasses and fresh cuts of pork and will require labeling. USDA's Food Safety and Inspection Service is considering petitioning the FDA to approve high-dose irradiation of chicken to control Salmonella.

FDA has been extremely cautious in moving to approve irradiation of food. The FDA and members of Congress have received many comments expressing concern that irradiation of food may not be safe. Based on government and private tests conducted now for more than three decades we believe these concerns to be unfounded. However, such concerns show that there is a need for the government to give more visible support for food irradiation, and perhaps even more important, the government must take a role in the education of the consumer. Such educational efforts by the industry alone could be perceived by the consumer as self serving.

Within the past decade EPA has cancelled or suspended the registrations of a significant number of valuable and widely used pesticides. With expanded animal testing of pesticides and further advances in analytical chemistry, food producers are likely to be faced with additional losses of important pesticides in the future. Moreover, the comprehensive premarket testing requirements imposed under the 1972 amendments to the Federal

Insecticide, Fungicide and Rodenticide Act (FIFRA) have substantially increased the time and expense, and correspondingly reduced the incentives, for development of new pesticides for minor use crops which are most of the crops produced by our members.

Although NFPA believes that judicious use of pesticides will continue to be essential to production of economical and wholesome food, these recent developments demonstrate the need for increased efforts by both government and private industry to develop safe and effective nonchemical pest controls. NFPA and its members believe that irradiation is one of the most promising alternatives to pesticides.

All new food processes were questioned extensively by consumers before acceptance and widespread use. Canning, freezing, pasteurization, microwaving were new technologies whose safety and efficiency were questioned. Consumer acceptance of irradiated food will also be an evolutionary process. We believe that irradiation, on the basis of FDA approval and increasing use, will, like earlier processing technology, ultimately be viewed as safe, effective and beneficial to consumers.

At this time I would like to direct my testimony to the legislation currently before this subcommittee. This is H.R. 696 introduced by Rep. Sid Morrison (R-Wash.) on January 24, 1985. This legislation contains express findings providing important recognition that food irradiation is a process much like canning or freezing, that irradiation is a valuable alternative to many

pesticides, and that public understanding of irradiation is essential to eliminate unfounded fear and suspicion.

Although H.R. 696 amends section 409 of the Food, Drug, and Cosmetic Act (the Act) so that irradiation is defined as a food process rather than a food additive the bill also contains a long series of amendments to section 409 separately listing irradiation in each instance in which the term "food additive" appears. Although our understanding is that there is no intention of making any substantive change in section 409 except to highlight that irradiation is not the same as other food additives, the lengthy amendments to that section are cumbersome and could create confusion or lead to misinterpretation. If the purpose is to have FDA continue regulating irradiation as if it were an additive although the bill changes the definition to a process, it would be simpler to leave section 409 untouched particularly since section 201(s) of The Act defines "food additive" to include "any source of radiation intended for any such use."

The Morrison bill would actually add a paragraph (bb) to section 201(s) that would define "food irradiation process" in detail. Our suggestion would be simply to amend the current 201(s) by adding "any source of irradiation" following the use of the word "substance" and deleting "and including any source of radiation intended for any such use" at the end of the first parenthetical phrase.

Amended 201(s) would read:

> The term "food additive" means any substance and any source of irradiation the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance and any source of irradiation intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food;) ~~and including any source of radiation intended for any such use~~), if such substance or source of irradiation is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance and any source of irradiation used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, except that such term does not include--

Despite the fact that the Morrison bill really does not alter current FDA regulatory power over food irradiation, we

NOTE: Language to be added has been underscored, that to be deleted crossed out.

believe that it would provide a valuable mechanism to promote irradiation research and development and to foster greatly needed consumer education. This legislation would also promote rational and consistent use of food irradiation and reduce unwarranted burdens on commerce by preempting state and local food irradiation regulations different than or in addition to those imposed by FDA.

However we are concerned that one of the "Findings and Purposes" listed under section 2 might be misunderstood to imply that additional research is required to ensure that irradiation is a safe food process. As we and other witnesses have stated there has already been extensive research and testing demonstrating that this process is safe.

An area of real concern to the food processing industry is the negative reaction by the consumer to anything that may be connected with nuclear power. For this reason we question the appropriateness of section 5 of H.R. 696 in what is supposed to be legislation to promote a new food processing technology. Section 5 deals solely with the "Leasing of Nuclear Byproduct Material for Food Irradiation" and we do not believe it belongs in this bill. For the same reason we believe paragraphs (11), (12) and (13) should be omitted from section 2, "Findings and Purposes:"

> (11) there is an acute shortage of United States source material required for food irradiation process and current supplies are unable to meet projected demand;

(1) the Federal Government owns byproduct materials as part of our defense nuclear waste programs;

(2) a significant return on investment can come back to the United States Treasury through the lease of irradiation source materials to private and public agencies;"

The main reason for any delay in the advancement of irradiation as a food process technology will be the lack of consumer acceptance. For this reason we believe that any legislation that may be necessary to ensure proper handling of "source materials" should be handled by separate legislation.

The American Medical Association, the World Health Organization and the American Council on Science and Health have already endorsed irradiation as a safe food process. The technology is already widely used in hospital facilities especially for patients on immunosuppressive drugs who are required to have a diet free of microbiologic contamination.

Finally, as I have stated we as an association have more than a passing interest in food irradiation. We are presently working with the U.S. Department of Energy (DOE) on a cooperative agreement which would provide us a nuclear agricultural commodities irradiator (GACI) which would be built next to our food research laboratory in California. Our present laboratory facilities in California, Seattle and Washington, D.C. enable us to do research in all types of food processing and packaging. An irradiation facility next to our California laboratory would

enable us to study the interaction between different types of food processing: for example, irradiation and thermal processing or irradiation and freezing.

DOE involvement in this project is part of the Byproducts Utilization Program which has the goal of developing and encouraging commercial use of DOE byproducts such as Cesium 137. This demonstration project was created by Congress as an ideal way to assess the feasibility of this type of technology transfer. DOE has said that the use of radiation to treat foodstuffs would constitute a very important evolution in basic food processing and could do much to reduce postharvest losses of foods, increase international trade potential, and eliminate health-threatening microorganisms in food.

We have not signed a final agreement with DOE but we are working with them toward that goal and look forward to participating in food irradiation research.

Presented by Harry C. Mussman, D.V.M., Ph.D.
Chairman

COALITION FOR FOOD IRRADIATION
Testimony on H. R. 696
Before the
House Agriculture Committee
Subcommittee on
Department of Operations, Research and Foreign Agriculture
November 18, 1985

On behalf of the Coalition for Food Irradiation, I appreciate the opportunity to present testimony today on the potential benefits food irradiation technology offers the consuming public. My name is Dr. Harry C. Mussman, and I am the Executive Vice President for Scientific Affairs of the National Food Processors Association, and serve as Chairman of the Coalition for Food Irradiation, a group of food industry, consumer and technical interests formed to foster consumer understanding and acceptance of food irradiation.

The Coalition's formation last year was based on the premise that the greatest obstacle to widespread commercial use of food irradiation was the uncertainty regarding consumer acceptance of the process. Surveys have shown that without some explanation of the process, consumers initially display fear and mistrust upon hearing about food irradiation. In addition, a great deal of misinformation has been communicated to the consuming public about food irradiation. Through formation of the Coalition, the food industry fought to remedy these problems by disseminating more balanced and credible information to the public.

The association with which I am associated invited other trade associations and food processing companies to join together in support of this consumer education campaign. This resulted in the formation of the Coalition for Food Irradiation, whose members include food companies such as Beatrice, Campbell Soup, General Foods and Del Monte. Other members of the Coalition include

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The Coalition for Food Irradiation is a broad-based group of food industry, consumer and technical interests formed to educate the public and inform Congress and the regulatory agencies on the food irradiation process.

packaging companies such as DuPont and spice interests like McCormick. In addition, trade associations representing most major food industry groups are members of the Coalition. Without question, the Coalition for Food Irradiation represents the most broad-based consumer education campaign ever launched by the food industry in support of a food preservation technique.

The Coalition's broad-based membership suggests the variety of ways in which irradiation technology could be employed by the food industry. The fresh fruit and vegetable and spice industries could use irradiation as an alternative to chemicals and pesticides to treat and disinfest crops. The meat and poultry industries could use irradiation to eliminate microorganisms and parasites that cause disease. And the processed food industry could employ the technology to sterilize packaging materials or combine the treatment with other processes to develop new, nutritious, shelf-stable products.

The benefits of the process to the American public are many. Consumers will be able to buy products that stay fresher longer, since the process can extend the shelf-life of some foods by preventing sprouting, retarding mold and killing many spoilage bacteria. Despite existing health and safety standards and warnings to consumers about proper food handling, disease-carrying bacteria such as Salmonella and parasites such as Trichinella spiralis harm a number of individuals each year. Widespread use of food irradiation could substantially reduce these risks and make the food supply safer. Irradiation can also open new export markets for U.S. food commodities, expanding commercial opportunities for American farmers and food processors.

In addition, food irradiation is viewed as a means for easing world hunger. By substantially retarding spoilage, irradiation will allow many food items that now spoil quickly to be treated and shipped to needy countries or to be grown, irradiated and stored in the countries themselves. This is especially significant for countries in which refrigeration is not commonly available, such as those in Africa.

The Coalition believes that the safety concerns associated with food irradiation technology at levels now being considered by FDA have more than adequately been put to rest. In the over thirty years during which food irradiation has been studied, conclusive research has determined that:

- Irradiation does not make foods radioactive, since the energy travels through the food without leaving any residues or radioactivity;
- Irradiation does not create harmful new substances in food, and the changes in food resulting from low-level irradiation are too minute to affect the safety of the food product;
- Irradiation does not create new strains of microbes which become resistant to treatment in the future; and
- Irradiation does not significantly affect the nutritional quality of foods, even at high levels.

It is important to recognize that the food industry is conservative by nature, unwilling to jeopardize its relationship of trust with consumers by employing a controversial new technology. However, leaders of the food industry are viewing food irradiation as a safe, beneficial and economical technology whose time has come. The thirty plus companies and trade associations that

support the work of the Coalition are publicly backing the process in the hope that much of the misinformation being circulated on food irradiation can be countered, and the negative image of the technology can be dispelled.

While the Coalition is not a lobby group, it does support legislation or regulatory initiatives that serve to promote the commercial growth of food irradiation. While I will leave it up to other members of this panel to comment on the specific provisions of Representative Sid Morrison's bill, H. R. 696, on behalf of the Coalition I would like to voice support for the overall intent of the legislation.

A copy of the Coalition's position paper on food irradiation has been submitted to the subcommittee for the record. I thank you for this opportunity to testify, and I would be happy to answer any questions you might have.

(Attachments follow:)

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Why Food Irradiation Now?

A White Paper on Food Irradiation and What it Means to Consumers

Prepared by
Coalition for Food Irradiation

Summary

Today there is growing interest by the food industry, government and consumers in the use of food irradiation to kill harmful insects, prevent disease and keep food fresher longer. This interest has been stimulated by growing public concern over chemicals used in foods. While food irradiation technologies have been around for more than 50 years, only recently have they become cost effective and gained prominent attention as potentially safer ways of protecting food products and public health.

This paper looks at recent developments in food irradiation processing and discusses the issues that lie ahead.

The Coalition for Food Irradiation is a broad-based group of food industry, consumer and technical interests formed to educate the public and inform Congress and the regulatory agencies on the food irradiation process.

Why Food Irradiation Now?

The Growing Interest in Food Irradiation

Growing public concern over the use of chemical fumigants to treat American food supplies has raised new interest in the use of irradiation technologies. Publicity has linked chemicals, food and health in a negative and alarming manner. Increasingly, calls are heard for government action to protect the public health from potentially dangerous chemicals.

The most recent catalyst for government action were laboratory studies showing that ethylene dibromide (EDB), a once widely-used post-harvest fumigant, may be carcinogenic for a number of animal species. EDB has been banned by the federal Environmental Protection Agency (EPA). Methyl bromide, another post-harvest fumigant, has also come under regulatory scrutiny by EPA. Ethylene oxide, also a fumigant, is suspected of causing health problems and recently the Occupational Safety and Health Administration drastically reduced its exposure limits.

As a result of this activity, continued use of many chemical treatment methods has been thrown into question. Now a wide variety of industries -- from food to hospital -- have begun seeking non-chemical alternatives.

Given the reduced number of chemicals and pesticides available to protect food and crops from insect infestation, the food industry must develop new alternatives to assure the availability of nutritious and safe food supplies. The food industry is now investigating various techniques -- irradiation, repeated dipping of commodities in hot water (double dip treatment), cold treatment and use of alternate chemicals. No single method is a panacea or effective for all foods. Food irradition, however, has been shown to be especially promising for many uses.

What is Irradiation?

Irradiation refers to the exposure of substances to radiant or light energy. We already use radiant energy in food preparation. Both broiling and baking are processes that use infrared radiation, and microwaves are used increasingly in cooking.

The form of radiant energy used in food irradiation is known as picowaves. These can be gamma rays, x-rays or electrons -- any wave of very short length that is able to penetrate foods or food packaging easily. Picowaves act by disrupting cell components thus killing harmful micro-organisms or insects without raising the temperature of the food.

The process of irradiating food is very simple. Food products are put on a conveyor belt-like system that carries them through a chamber containing a machine or compertment that emits a controlled level of energy. The dose of irradiation a product receives is based on the amount of time it is exposed to the radiation source. After the food products have been irradiated, they can be immediatley handled or consumed.

How Does Food Irradiation Work?

In discussing food irradiation, three food irradiation dosage ranges are commonly referred to, depending on the application:

- o Low-dose (up to 100 kilorads)*
  - -- Inhibits the growth of sprouts on potatoes and other foods.
  - -- Kills insects and larvae that can be found in wheat, flour, fruits, and vegetables after harvesting.
  - -- Slows the ripening process, keeping fruits and vegetables fresher for weeks.
  - -- Kills certain harmful parasites associated with foods.
- o Medium-dose (100-1,000 kilorads)
  - -- Dramatically reduces the number of or eliminates certain microbes and parasites that cause food to spoil.
  - -- Reduces or eliminates a number of micro-organisms and parasites that cause disease.
- o High-dose (1,000 - 5,000 kilorads)
  - -- Sterilizes food for a variety of uses, such as meals for hospital patients who suffer from immunal disorders and can only eat bacteria-free foods.
  - -- Eliminates some disease-causing viruses.

The first U.S. patent application for food preservation through irradiation was filed in 1905. Today, the value of radiation technologies to ensure food safety is recognized worldwide. Twenty-one countries have approved irradiation use on 31 foods with no evidence of adverse health effects. In fact, in many parts of the world, food products preserved through irradiation are considered healthier since they are likely to remain fresher for longer periods of time.

Irradiation has been studied closely by international groups. In 1980, the Joint Expert Committee of the Food & Agriculture Organization of the United Nations, the International Atomic Energy Agency and the World Health Organization concluded that "irradiation of any food commodity up to an overall dose of 1,000 kilorads presents no toxicological hazard."

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* A kilorad is one thousand rads. A rad is a unit of measure for absorbed dose of ionizing radiation per unit mass of irradiated material. Dosage can also be measured in Grays with 1 Gray equal to 100 kilorads.

Is Food Irradiation New?

The group went on to conclude that the process "introduces no special nutritional or microbiological problems." In 1983, the Codex Alimentarius Commission, a group that develops international food standards, adopted a standard of 1,000 kilorads for food product irradiation.

In the United States, interest is clearly growing:

- The American Medical Association and the Institute of Food Technologists have endorsed low-dose food irradiation processes.
- For more than 20 years, the Food and Drug Administration has allowed the irradiation of potatoes for sprout inhibition and the irradiation of wheat and wheat flour for insect control. More recently, FDA approved the use of irradiation for spices and for pork to destroy many harmful micro-organisms.
- Recently the FDA approved the use of low-dose irradiation to eliminate trichinosis in pork.
- American astronauts eat foods sterilized by radiation.
- Hospotals irradiate food for patients with immune system disorders or those going under immunal suppressive therapy following organ transplants.
- Congressional hearings have recently focused attention on irradiation as a promising alternative to potentially hazardous chemical pesticides.

Is Food Irradiation Safe?

According to the Food and Drug Administration's Center for Food Safety and Applied Nutrition, "many years of research on the irradiation process have shown that the proposed levels of irradiation are safe." *

Health concerns about food treated with radiation revolve around four questions:

- Is irradiated food radioactive?
- Will irradiation create new substances in the food which are harmful?

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* Testimony of Sanford A. Miller, Director, Center For Food Safety and Applied Nutrition, Food and Drug Administration, before the Committee on Science and Technology, July 26, 1984.

- Will irradiation create new strains of microbes which become resistant to treatment in the future?

- Will irradiation diminish the nutritional quality of the treated food?

Let's look at each question.

Is Irradiated Food Radioactive?

The most commonly asked question about food irradiation is whether it will increase human exposure to radiation. This issue was studied extensively by the National Bureau of Standards and the National Academy of Sciences in the early 1960's. They concluded that consumers will not be exposed to additional radiation by eating irradiated food because the process is not of sufficient intensity to induce radioactive changes; thus energy passes through the food products leaving no residue or radioactivity. A simple analogy is that consumers run no more risk of being exposed to radioactivity from irradiated food than from a briefcase that has been passed through an x-ray scanning machine at an airport.

Will Irradiation Create Harmful New Substances in the Food?

Concern has been raised that irradiation will produce in foods new chemical compounds with unknown health effects. Increasingly more refined scientific techniques have permitted careful study of this issue. FDA and other researchers have concluded that changes in food resulting from low-level irradiation are too minute to affect the safety of the food product.

Generally, exposing materials to air, heat (roasting or frying), or any type of radiant energy -- whether sunlight or oven heat -- changes the product's molecules into a variety of compounds. These compounds, or radiolytic products, are formed when any of these types of energy interact with fat, protein, or carbohydrates in the food. The higher the radiation dose, the greater the change in the food molecules and the higher the yield of the radiolytic products.

The FDA and others indicate that radiolytic products are not new substances. These compounds are well-known, and many are chemically similar to compounds naturally found in foods. In fact, at low doses, irradiation develops fewer radiolytic products than can be found in a barbequed steak.

FDA experts have concluded:

> ...at the radiation doses FDA has proposed for treatment of foods, the irradiated food is virtually indistinguishable from the equivalent non-irradiated food, and the types and amounts of radiolytic products formed are such as to make the foods indistinguishable with respect to safety. *

The question of "unique" radiolytic products (URP) takes on added importance as the irradiation dose increases. While the search for these agents has thus far been unsuccessful, when and if URPs are isolated, their potential hazard can and will be assessed. However, URP's are not in question at the levels proposed for commercial use.

Will Irradiation Of Foods Create New Strains Of Microbes Which Become Resistant To Treatment In The Future?

Another concern that has been raised is that harmful microbes which create spoilage and cause disease might become resistant to irradiation and give way to new strains of harmful organisms. Researchers have found that the radiation dose required to completely eliminate many disease causing bacteria and their spores is below 500 kilorads -- well under the 1,000-kilorad level considered safe by the World Health Organization.

Most investigators consider the probability of developing radiation-resistant strains of bacteria to be remote because irradiation is not an efficient mechanism to create new strains nor does it provide an environment that would enable new strains to survive.

Will Irradiation Of Foods Diminish Nutritional Quality Of Treated Food?

Just about anything done to foods -- including harvesting -- results in some overall nutrient loss. Because irradiation is a "cold process" (involving no heat as opposed to thermal processing), the nutritional quality of irradiated food is essentially equivalent to that of fresh food products. Only very minute losses of niacin, thiamine, riboflavin and beta-carotene have been noted.

Are There Benefits to Food Irradiation?

Until now, we have talked about food irradiation only as an alternative to chemical treatment. But food irradiation offers a number of other benefits.

Food Irradiation Can Keep Foods Fresher Longer

Irradiation of foods keeps some products fresher longer. The process can extend shelf life by preventing sprouting, retarding mold, and killing many spoilage bacteria. For example, irradiated strawberries remain in good condition for three to four weeks as opposed to approximately one week without treatment. Irradiation also prolongs the shelf life of many other foods including poultry, meat and a variety of fruits and vegetables. The process preserves the food by eliminating bacteria and insects which cause spoilage without any noticeable changes in the composition that gives fresh produce its appeal.

* See Sanford A. Miller testimony.

Food Irradiation Can Improve World Food Supplies and Open New Markets for U.S. Farmers

A driving force behind international acceptance of irradiation is its potential for easing world hunger. The United Nations estimates that over 25 percent of the world's harvest is now lost to spoilage and waste. By substantially retarding spoilage, irradiation will allow many food items that now spoil quickly to be treated and shipped to needy countries or to be grown, irradiated and stored in the countries themselves. This is especially significant for countries in which refrigeration is not commonly available, such as those of the African continent and elsewhere.

At the same time, irradiation will open new export markets for U.S. food commodities, expanding commercial opportunities for American farmers and food processors. For example, Japan will not allow apples to be imported unless they are treated for codling moth. Since EDB is no longer an available treatment, irradiation is a feasible method that may open up Japanese markets to American apple growers.

Food Irradiation Offers Real Health Benefits

Food irradiation makes food safer by destroying micro-organisms that can cause food poisoning and parasites that can cause disease. At low-to-medium dose levels, irradiation kills Salmonella and other bacteria that cause disease as well as the parasite Trichinella spiralis found in some undercooked pork which can lead to trichinosis in humans.

Each year, these parasites and diseases harm a number of individuals, despite existing health and safety standards and warnings to consumers about proper food handling. Irradiation has the potential to substantially reduce the public risk from these health hazards.

Summary of Benefits

After 50 years of practice and research, indications are that food irradiation offers great potential as an alternative to the use of EDB and other pesticides. A number of features make food irradiation particularly attractive:

- Food irradiation is safe for use at the levels now proposed by the food industry and government.
- Food irradiation can be an effective alternative to some chemical fumigants, and leaves no residue on the food.
- Food irradiation keeps many foods fresher longer.
- Food irradiation makes food safer to eat by destroying micro-organisms that can cause food poisoning and parasites that can cause disease.
- Food irradiation can improve world food supplies by eliminating much of the waste caused by spoilage.

- Food irradiation improves the export potential for many foods.

Many challenges lie ahead before food irradiation can become a significant commercial reality:

- Research must be done on each food to determine the dose and the irradiation parameters which will effectively kill harmful organisms without adversely affecting the marketability of the product.

- Capital and operating costs will have to be studied carefully to determine the commercial viability of using irradiation.

- As we consider using higher doses of irradiation and adding new amounts and types of food to the list of products that can be irradiated, important questions regarding chemistry and food safety must be addressed and continuously re-examined.

These issues are in large part technical problems. If industry and government want to solve them, they will. The biggest challenge in the past was cost. Today it is consumer acceptance.

The public is inherently suspicious of a new process, particularly when the same technology has caused concern previously when used in an entirely different manner. For many, the concept of food irradiation stirs up concerns from other uses of nuclear technology. Few realize that food can be irradiated by high-energy electron generators -- which do not use radioactive materials. Most also are not aware food irradiation has been used safely in hospitals and by our astronauts. Many do not understand irradiation does not produce a radioactive product.

A Department of Energy National Port Producers Council study of consumer reaction found significant concern about the use of food irradiation. While much of this fear is based on faulty information, the concerns are real and need to be met in public forums with facts and credible evidence. DOE warns, "more effective consumer information will be necessary to reduce the significant concern that exists within the population."

There is little doubt of the need for public education about food protection through irradiation. So far, public discussion has led to confusion and concern.

At the same time, the process and its potential should not be oversold. Food irradiation is a useful technology which has the potential for delivering safer food along with other substantial benefits. But it is only one of several technologies now being investigated for use in improving our supply of nutritious and safe food. For some foods, irradiation will not produce a desirable product. Other means of treatment and preservation will be necessary.

For now, government, industry and consumers need to keep an open mind about the technologies available to make food products safe and appealing. We need to weigh potential risks along with potential benefits. With irradiation, as with other technologies, we will need to move forward methodically to ensure that the technology delivers the best benefits to society.

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raising the temperature of the food, causing any radioactivity to leave detectable residues.

A major public advantage of food irradiation is that the process helps keep foods fresher longer. Irradiated strawberries, for example, remain in good condition for three to four weeks, as opposed to approximately one week without treatment.

Irradiation also makes foods safer to eat by destroying microorganisms that can cause food poisoning and parasites that can cause disease. "Each year, parasites and food-borne disease have a significant number of individuals, despite existing health and safety standards and warnings to consumers about proper food handling," said Rusmore. "Irradiation has the potential to reduce substantially the public risk to health hazards such as toxoplasmosis, trichinosis and salmonellosis."

Rusmore also cited the technology's potential to ease world hunger. The United Nations estimates that over 25 percent of the world's harvest is now lost to spoilage and waste. By substantially retarding spoilage, irradiation will allow many food items that now spoil quickly to be treated and shipped to needy countries or to be grown, irradiated and stored in the countries themselves. This is especially significant for countries in Africa and Asia where refrigeration is not commonly available. At the same time, irradiation can open new export markets for U.S. food commodities, expanding commercial opportunities for American farmers and processors.

The FDA is expected soon to release a final ruling to allow for irradiation of fresh fruits and vegetables. Food irradiation is already

(more)

used in the U.S., having been approved to use on pork and to destroy harmful microbes in spices, inhibit sprouting in potatoes, and treat food for hospital patients with immune system disorders. American astronauts eat meat and poultry preserved by irradiation. The American Medical Association has also endorsed the use of food irradiation.

"Food irradiation is a technology whose time has come," said Russano. "It is a beneficial means of processing foods and should be treated as such under federal law."

The Coalition for Food Irradiation was formed in January 1985 to educate consumers on the benefits of food irradiation technology. The Coalition is composed of over 30 companies and associations from the food industry.

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STATEMENT

of the

AMERICAN MEDICAL ASSOCIATION

to the

Subcommittee on Department Operations,
Research and Foreign Agriculture
Committee on Agriculture
United States House of Representatives

Presented by

A. Harold Lubin, M.D.

Re: H.R. 696, the Federal Food Irradiation Development and Control Act of 1985

November 18, 1985

Mr. Chairman and Members of the Committee:

My name is A. Harold Lubin, M.D., and I am Director of the Department of Foods, Nutrition, and Personal Health of the American Medical Association. Accompanying me is Thomas Wolff of the AMA's Department of Federal Legislation. The AMA appreciates the invitation to testify today concerning H.R. 696, the Federal Food Irradiation Development and Control Act of 1985.

H.R. 696 would amend the Federal Food, Drug, and Cosmetic Act to redefine food irradiation as a "process" under the Act. Currently, food irradiation is included under the Act's definition of "food additive." "Food irradiation process" would be defined as a food treatment in which ionizing energy is applied to food to inhibit or destroy bacteria and other microorganisms which cause spoilage, to inhibit sprouting, to

retard the post-harvest ripening of food, and to improve the food's functional properties. The Food and Drug Administration would retain its authority to regulate food irradiation and no state or political subdivision would be allowed to establish any food irradiation requirement which is "in addition to or different from" any FDA requirements.

H.R. 696 also would create a Joint Operating Commission for Food Irradiation within the Department of Agriculture. The Commission would be composed of eight members including representatives of seven government agencies and one person representing the interests of the general public. The Commission would coordinate and review all federal research, development, and demonstration activities relating to food irradiation and collect and consolidate the data concerning food irradiation produced by federal agencies. In addition, the Commission would coordinate informational exchange and educational activities concerning food irradiation with appropriate federal agencies, states, private organizations and the general public. The Commission would also promote investment by private companies in the development and application of food irradiation and attempt to foster greater public understanding of the process of food irradiation. Finally, the Commission could petition the FDA to expand the scope of regulation allowing for commercial application of food irradiation.

The AMA supports H.R. 696. Many years of international experience have demonstrated that foods irradiated at levels of up to 10 kilograys (1,000 kilorads) are safe to eat. In fact, in 1980, the Joint Expert

Committee on the Wholesomeness of Irradiated Foods, sponsored by the Food and Agriculture Organization (FAO) of the United Nations, the International Atomic Energy Agency, and the World Health Organization (WHO), concluded that "the irradiation of any food commodity up to an overall average dose of 10 kGy (1,000 kilorads) presents no toxicological hazard" and "...introduces no special nutritional or microbiological problems." The Codex Alimentarius Commission, a United Nations organization under the auspices of the WHO and the FAO has recommended unconditional clearance for foods irradiated at a dose not exceeding 10 kGy (1,000 kilorads).

Food irradiation leaves no residue in food. Moreover, while food irradiation does cause slight chemical and physical changes in food, these changes are no more significant than the changes that occur from other accepted food processes such as boiling or freezing. Over 30 years of study using sophisticated analytical techniques to ascertain what unique radiolytic products (URPs) may be formed in irradiated food have failed to detect the production of any URPs of toxicological concern.

Food irradiation produces no significant reduction in the nutritional quality of food. In addition, it has a number of important potential applications. Food irradiation is effective in killing the microorganisms that cause food spoilage. Thus, food irradiation could extend the storage life of numerous perishable foods thereby increasing the productivity of U.S. food processing and distribution and opening new export opportunities.. These factors are very significant since a considerable amount of the world's food supply is lost each year through spoilage.

Food irradiation may also be a viable alternative, in the post-harvest disinfestation of fruits and vegetables, to pesticides about which health concerns have been raised. Moreover, it may be effective in controlling trichinae in fresh pork and salmonella in red meats, poultry and fish.

In our view formal official reclassification of food irradiation is important in terms of public acceptance of the fact that food irradiation is a safe process, not a potentially hazardous food additive. It is important to note that food irradiation does not make the irradiated food radioactive since it is done at energy levels well below those required to induce radioactivity. We believe it is appropriate, however, that the bill would not eliminate the FDA's authority to regulate food irradiation. This would offer to the public assurance of continued protection.

The AMA supports the establishment of the Joint Operating Commission for Food Irradiation. The Commission would perform the vital function of coordinating research concerning food irradiation that currently is fragmented among many federal agencies. The Commission would also have the important function of promoting public understanding and acceptance of food irradiation. This would entail informing the public of the many potential benefits of food irradiation and addressing any unwarranted concerns regarding the process. Finally, we believe it is appropriate for the Commission to have the authority to petition the FDA if it believes that the commercial application of food irradiation should be expanded.

We also support the provision in the bill that would preempt state and local laws that are in addition to or different from the FDA's requirements concerning food irradiation. We believe that the regulation of food irradiation should be uniform throughout the country in order to ensure that the nationwide marketing of irradiated food is not impeded by inconsistent or conflicting state and local government requirements.

The AMA recognizes that questions must still be addressed concerning whether food irradiation will be a cost-effective process for some commercial applications. Moreover, additional educational efforts by the food industry, the government, and health professionals may be needed to help ensure widespread consumer acceptance of the use of food irradiation. However, we believe that enactment of H.R. 696 is an important first step in promoting the use of the promising technology of food irradiation. We support early adoption of this legislation.

Mr. Chairman, the AMA appreciates your invitation to testify before the Committee and stands ready to work with you concerning this important issue.

JHS/cmb

2230p

NCSFI

National Coalition to Stop Food Irradiation

Phone: (415) 56N-CSFI **P.O. Box 59-0488, San Francisco, CA 94159**

TESTIMONY FOR THE PUBLIC RECORD ON H.R.696,"FEDERAL FOOD IRRADIATION DEVELOPMENT AND CONTROL ACT OF 1985," BEFORE THE HOUSE AGRICULTURE SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH AND FOREIGN AGRICULTURE, NOVEMBER 18, 1985, ROOM 1302, LONGWORTH HOUSE OFFICE BUILDING, WASHINGTON, D.C. 20515.

HOUSE SUBCOMMITTEE ON DEPARTMENT OPERATIONS, RESEARCH & FOREIGN AGRICULTURE
ROOM 1301
LONGWORTH HOUSE OFFICE BUILDING
WASHINGTON, D.C. 20515

THE HONORABLE BERKELEY BEDELL AND DISTINGUSIHED REPRESENTATIVES,

Good morning. My name is Denis Mosgofian. I am an occupational health instructor to the Graphic Communications Industry, and am a fine arts and industrial photolithographer by trade. I am here today testifying on behalf of the NATIONAL COALITION TO STOP FOOD IRRADIATION, of which I am co-founder and director.

It is our view that H.R. 696 is a deeply flawed piece of legislation. It is flawed in its premises, assumptions and intent.

First, H.R. 696's assertion that "irradiation of food... is recognized by international authorities and the Department of Health and Human Services as safe and wholesome" is neither proof of its safety nor sufficient grounds for this legislation. Until recently, international authorities and HHS recognized DES, bendectin, thalidimide, sulfites and asbestos as safe and wholesome. It is important to note that what is international to one body is national to another, and local to others. We are impressed by proofs of safety, and not by reference to authorities. At this point there is no firm proof of safety.

The second flawed presumption on which H.R. 696 sits is that "irradiation is a process, much like cooking in a microwave oven, boiling or freezing." This could not be further from the truth. Gamma radiation is ionizing energy; boiling, freezing and microwaving are not. Ionizing(gamma) radiation indiscriminately disrupts the electron structure of target tissues, and through free radical chemistry, creates new chemical bonds, and unique radiolytic products. Ionizing gamma radiation precedes cooking; it does not replace it. Gamma radiation's unique radiolytic products will be added to the varied hazards of cooking, and will increase the total toxic load people must carry in our society. Moreover, it is unknown what the cooking of irradiated foods will produce. But gamma irradiation is definitely not "like cooking".

We must keep in mind the method by which gamma radiation kills, by molecular disruption and free radical chemistry, in order to appreciate its distinction from other food treatments. It is what ionizing radiation does that matters. H.R. 696 glosses this over.

Gamma irradiation adds adulterative compounds to food which were not there originally. It was with this understanding that Congress adopted the 1958 Additives Amendment to the Food, Drug and Cosmetic Act, and explicitly included food irradiation in the food additive classification. H.R. 696 seeks to void that Congressional intent by falsely declaring gamma radiation is like boiling, etc..

The legislative intent in H.R. 696 of changing food irradiation from "additive" classification to "process" is to remove irradiated food from FDA rigorous scrutiny, testing requirements and labeling obligations stipulated by the 1958 Additives Amendment, and provide the FDA with a foundation and the impetus to confidentally continue their no-retail-label Rule Making process through the Federal Register. H.R. 696 seeks to take the FDA out of the picture while pretending otherwise.

In terms of "process"(baking, boiling, freezing) there is no FDA safety review, except as to low acid foods for acidity,and except as to poor sanitation for microbacterial contamination. How can any responsible legislator endorse the institutionalizing of this casual procedure for ionizing radiation? This is what H.R. 696 asks you to do.

The burden of food safety responsiblity rests with the government, not the consumer. H.R. 696 would institutionalize irresponsibility in Administrative food scrutiny and simultaneously limit citizen review by precluding state and local elected officials from establishing more stringent consumer protection than may be established by the proposed Joint Operating Commission for Food Irradiation. H.R. 696 fails by omission to spell out a single consumer protection, and in the same legislation seeks removal of existing protections by changing food irradiation to a "process".

We note that H.R. 696 ignores the 1968 FDA ban on irradiation of pork and its findings of significant adverse effects on reproduction, mortality, weight depression, reduced red blood cell count, increased cataracts, testicular tumors, pituitary carcinomas and production of antinutrient factor. It appears to us from the FDA perfunctory July 22, 1985 Final Ruling[1] authorizing irradiation of pork[2], that the FDA has chosen too, to ignore its own 1968 findings.

The significant findings of polyploidy (chromosomal damage) in malnourished children fed irradiated wheat[3], and findings of increased aflatoxin production after gamma irradiation[4], should give each of you reason to want more definitive information than self-serving industry hyperbole and explanations why each negative finding is somehow not applicable.

With respect to the "international authorities", a Japanese doctor, Takahasi Kosei, re-analyzed the toxicological data used by the Joint Committee of FAO/IAEA/WHO and found that unconditional acceptance of irradiation of potatoes, onions, wheat and rice was not supported.

Dr. Takahashi Kosei also concluded that"the theoretical approval on the safety of all kinds of food irradiated at a dose of up to 1,000,000 rads was not supported either from the view point of radio-chemical studies on food stuffs as a complex system, or from the experimental results."[5] His report "cast grave doubts on the reliability of scientific activities of international organizations such as FAO, IAEA, and WHO."

It appears to us H.R. 696 is designed to promote the Department of Energy By-Products Utilization Program proposal for nuclear waste management. This program is the promoting of a socially acceptable industry which will require the building of thousands of warehouses for America's nuclear waste.

Food irradiation depands upon a network of food irradiating plants. These are proposed to each house 3,000,000 curies of radioactive CESIUM -137(from weapons & power waste) and COBALT-60. H.R. 696's passage is needed to open the door for this program. As you can see, this program for food irradiating facilities will promote the widespread proliferation of radioactive waste. This will increase the likelihood of irreversible radioactive contamination of our communities and highways from inevitable human error and accident, miscalculation and negligence.

We need only recall the accident at the International Nutronics plant in Dover, New Jersey, the tritium leaks which contaminated the Tucson, Arizona school district kitchen(American Atomics), and the worker exposure through management error and decision, Radiation Technology, Rockaway, New Jersey, to get a glimpse of the pandora's box of nuclear horrors H.R. 696 opens. H.R. 696 further opens the door for the unloading of America's radioactive waste onto developing nations where it may be presumed environmental and occupational regulations and enforcement are less stringent than here in the USA. To launch the food irradiation industry, such proliferation of rad-waste is required. Yet it is by no means necessary to quality food production, and poses a planetary contamination threat second only to nuclear war.

Only a full technology assessment and environmental impact review of the ultra-hazardous food irradiation industry will offer us a firm beginning point for determining the actual consequences of launching food irradiation. For once launched, the effects will be irrevocable.

H.R. 696 is dangerous in its intention and alarmingly irresponsible. I urge you to reject it and food irradiation.

On behalf of the tens of thousands of members and supporters of all the members organizations of the NATIONAL COALITION TO STOP FOOD IRRADIATION, I wish to thank you for this opportunity to present testimony on a matter of grave importance to us all.

Respectfully,

Denis Mosgofian

Denis Mosgofian
co-founder, director

ENCLOSURES
DM:vg

REFERENCES:

(1) 21 CFR Part 179, Irradiation in the Production, Processing, and Handling of Food, FDA, Final Rule
(2) Alan T. Spiher, Jr., Food Irradiation: An FDA Report, FDA Papers, October 1968.
(3) C. Bhaskaram, M.D., and G. Sadasivan, M.Sc., M.B., B.S., M.Sc. Effects of feeding irradiated wheat to malnourished children, National Institute of Nutrition, Indian Council of Medical Research, Hyderabad-500007, India, Am.J.Clin.Nutr.28,1975
(4) A.F. Schindler, A.N. Abadie and R.E. Simpson Enhanced Aflatoxin Production by Aspergillus flavus and Asperfillus parasiticus after Ganna Irradiation of the Spore Inoculum, Journal of Food Protection, Vol. 43, Jan 1980
(5) Takahashi Kosei, M.D., Irradiation of the Food We Eat, A New Danger, Ampo, Vol. 15, No. 2, 1983, attached.

(Attachments follow:)

BARBARA BOXER
6TH DISTRICT, CALIFORNIA

COMMITTEE ON THE BUDGET

COMMITTEE ON
GOVERNMENT OPERATIONS

SELECT COMMITTEE ON CHILDREN,
YOUTH, AND FAMILIES

WHIP AT LARGE

Congress of the United States
House of Representatives
Washington, D.C. 20515

[redacted]

October 22, 1985

Seth Mosgofian
241 Terrace #5
San Francisco, CA 94117

Dear Mr. Mosgofian:

Thank you for your letter concerning the names of the harmful dyes mentioned in my "Capitol Report." I also appreciated your very kind words of support.

I agree with you that it would have been best to include the names of the dyes in my newsletter. For your information, the harmful dyes are as follows:

FD&C Red No. 3
FD&C Yellow No. 6
D&C Red No. 8, 9, 19, 33, 36 and 37
D&C Orange No. 17

I share your concern about the FDA's proposal to irradiate food and I have decided to oppose H.R. 695, "The Federal Food Irradiation Development and Control Act of 1985," because I would prefer to see more research done on the subject before the FDA forges ahead with its proposal.

Thank you once more for contacting me. Please do not hesitate to contact me in the future if I can be of assistance or if you have other concerns.

In friendship,

Barbara

BARBARA BOXER
Member of Congress

BB:deb

ALAN CRANSTON
CALIFORNIA

United States Senate

WASHINGTON, DC 20510

November 6, 1985

Mr. Ron Epelbaum
521 South 5th Street #4
San Jose, California 95112

Dear Mr. Epelbaum,

Thank you for your message about the Food and Drug Administration's proposal regarding the irradiation of food. I will appreciate your comments.

Under federal law, the irradiation of food is classified as a food additive. Irradiation is thus subject to the procedures applied to food additives under the Food, Drug and Cosmetic Act. Legislation has been introduced -- S. 288 in the Senate and H.R. 896 in the House of Representatives -- which would permanently classify irradiation of food as a food process rather than a food additive. I am opposed to this legislation. Removing irradiated foods from the scrutiny of the Delaney Act, as this measure would require, would leave food irradiation without any federal standards or oversight.

As you are aware, in February 1986, the FDA proposed to permit expansion of the approved uses of irradiation in food. The proposed would allow food manufacturers and food processors to use radiation to kill insects in fruits and vegetables and to extend the shelf-life of specific spices and vegetable seasonings. The proposed regulations set the limit of a dose of radiation for fruits and vegetables at 100 kilorads and 3 megarads for spices.

The Food and Drug Administration has not yet issued a final decision on this proposal. I have been in touch with FDA Commissioner Dr. Frank Young, requesting particular consideration of ongoing irradiated foods to be so labeled. Consumers should have adequate information to enable them to make informed choices in the marketplace.

I appreciate your keeping in touch with me.

Sincerely,

Alan Cranston

[illegible]

3. to add a new definition for food irradiation as a process in 21 USC § 321(s) (Section 201), as follows:

(s) The term "food irradiation process" means a food treatment to which ionizing energy is applied to raw agricultural commodities, processed foods, or other foods to destroy the organisms which cause infestation in food, to inhibit or destroy bacteria and other microorganisms which among other things cause food to spoil or make the food unwholesome, to inhibit sprouting, to retard the postharvest ripening of foods, and to improve the food's functional properties.

5. to change the procedures for obtaining an exception in 21 USC § 348(a)-(d) and (j) (Section 409), as follows:

Section 348. Food additives and food irradiation Process.—Unsafe food additives and food irradiation process exception for conformity with exception or regulation

(a) A food additive or food irradiation process shall, with respect to any particular use or intended use of such additives, or process, be deemed to be unsafe for the purposes of the application of clause (2)(C) or clause (3) of section 342(a) of this title, unless—

(1) it and its use or intended use conform to the terms of an exception which is in effect pursuant to subsection (c) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive or process may be safely used.

While such a regulation relating to a food additive or food irradiation process is in effect, a food shall not, by reason of having in or containing such an additive or having been treated by such a process in accordance with the regulation, be considered adulterated within the meaning of clause (2) of section 342(a) of this title.

Petition for regulation prescribing conditions of safe use; contents; description of production methods and controls; samples; notice of regulation

(b) (1) Any person may with respect to any intended use of a food additive, or food irradiation process file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, or the source of the food irradiation process, including for such additive, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, or the proposed procedure and methods for conducting the food irradiation process including all directions, recommendations, and sug-

gestions proposed for the use of such additive or process, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, or process, including full information as to the methods and controls used in conducting such investigations unless the level of the proposed food irradiation process has already been recognized to be safe by the Secretary. [NOTE: This sets the stage for the arbitrary use of administrative fiat by the F.D.A.'s "Rule Making Process."]

(2) Upon request of the Secretary, the petitioner shall furnish (or, in the case of a food additive, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish (without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for food irradiation process or the production of such additive.

(3) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used or, in the case of food irradiation process, such information as the Secretary requests.

(4) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

Approval or denial of petition; time for issuance of orders; evaluation of data; factors

(c) (1) The Secretary shall--

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing with respect to one or more proposed uses of the food additive or food irradiation process involved, the conditions under which such additive or process may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or to which such additive or process may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive or process may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive or process deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) the order required by paragraph (1)(A) or (B) of this subsection shall be issued within ninety days after the date of filing of the petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary--

(A) fails to establish that the proposed use of the food additive or food irradiation process, under the conditions of use to be specified in the regulation will be safe: Provided, That no additive or process shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives or food irradiation processes, to induce cancer in man or animal, except that this proviso shall not apply with respect to the use of a substance as an ingredient of food for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive or process will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive or process will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g) of this section) in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal; or

(B) shows that the proposed use of the additive or process would promote deception of the consumer in violation of this chapter or would otherwise result in adulteration or in misbranding of food within the meaning of this chapter. [NOTE: Foods exposed to gamma or ionizing radiation which are sold to retail consumers either unannounced or unlabeled are deceiving the consumers.]

(4) If, in the judgment of the Secretary, based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive or process will be safe, the Secretary--

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive or process is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect. [NOTE: There is certainly sufficient data available to show that irradiation of food does not produce the intended physical or other technical effect.]

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors--

(A) the probable consumption of the additive and of any substance formed in or on food because of use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

[NOTE: Why isn't the phrase "Food irradiation process" inserted here in (5) (A), (B), (C)?]

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive or food irradiation process, the conditions under which such additive or process may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

. . .

Exemptions for investigational use

(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive or food irradiation process and any food bearing or containing such additive or treated by such process intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

June 25, 1983, c. 675, section 409, as added Sept. 6, 1958, Pub.L. 85-929, section 4, 72 Stat. 1785, and amended June 29, 1960, Pub.L. 86-546, section 2, 74 Stat. 255; Oct. 18, 1962, Pub.L. 87-781, Title I, section 104(f)(1), 76 Stat. 785.

Domestic distribution; license; price limitations.

4. to change the intent of the provisions of the law governing use of nuclear by-product materials in 42 USC § 2111 as follows:

No person may transfer or receive in interstate commerce, manufacture, produce, transfer, acquire, own, possess, import, or export any byproduct material, except to the extent authorized by this section or by section 2112 of this title. The Commission is authorized to issue general or specific licenses to applicants seeking to use byproduct material for research or development purposes, for medical therapy, industrial uses, agricultural uses, or such other useful applications as may be developed. The Commission may distribute, sell, loan, or

lease such byproduct material as it owns to licensees with or without charge: Provided, however, That, for byproduct material to be distributed by the Commission for a charge, the Commission shall establish prices on such equitable basis as, in the opinion of the Commission, (a) will provide reasonable compensation to the Government for such material, at rates that reflect fair market value, (b) will not discourage the commercial or other use of such material or the development of sources of supply of such material independent of the Commission, (c) will encourage research and development, and (d) will encourage commercial applications of byproduct material as defined in section 11.e.(1), particularly as a source food irradiation process. In distributing such material, the Commission shall give preference to applicants proposing to use such material in the conduct of research and development, in commercial applications of food irradiation process, or in medical therapy. Licensees of the Commission may distribute byproduct material only to applicants therefor who are licensed by the Commission to receive such byproduct material. The Commission shall not permit the distribution of any byproduct material to any licensee, and shall recall or order the recall of any distributed material from any licensee, who is not equipped to observe or who fails to observe such safety standards to protect health as may be established by the Commission or who uses such material in violation of law or regulation of the Commission or in a manner other than as disclosed in the application therefor or approved by the Commission. The Commission is authorized to establish classes of byproduct material and to exempt certain classes or quantities of material or kinds of uses or users from the requirements for a license set forth in this section when it makes a finding that the exemption of such classes or quantities of material or kinds of uses or users will not constitute an unreasonable risk to the common defense and security and to the health and safety of the public. [NOTE: This working legalizes Food Irradiation as a formal Government program.]

5. to legitimize and institutionalize the U.S. Department of Energy's nuclear weapons By-Product Utilization Program as a means of linking the use of radioactive wastes to the irradiation of our food by private companies -- this is Food Fascism;
6. to grease the skids for the commercialization of Food Irradiation;
7. to use taxpayer money to create and sustain the Joint Operating Commission for Food Irradition within the Department of Agriculture and to mandate this Commission to "sell" Food Irradiation to the American public.

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Irradiation of the Food We Eat

A New Danger

by Takahashi Kosei

Introduction

The application of Gamma-ray irradiation techniques for the preservation of food was investigated after the Second World War by the US Army, the Atomic Energy Agency of the United Kingdom and the Government of the Soviet Union. Since 1970 the International Organization, FAO in Rome, IAEA in Wien and WHO in Geneva , has had a Joint Committee on the "Wholesomeness of Irradiated Food."

Having held four meetings by 1980, the Joint Committee suggested an unconditional dose of irradiation for the majority of usual foods from the standpoint of toxicology.

From a theoretical consideration, the Joint Committee also advocated unconditional acceptance of any food irradiated up to 1,000,000 rad and stated that no toxicological testing of food so treated was necessary.

In Japan food irradiation has been investigated by the "Research Group on Peaceful Application of Atomic Energy" since 1967 and irradiation of potatoes was cleared in 1972. At present potatoes are the only irradiated food which is sold on the market in Japan, though investigation on irradiated onion, wheat, rice and orange has already been conducted.

However, there is little confidence on the safety of irradiated foods. The following discussion is the result of the author's analyses of the data obtained from published papers, documentations of the WHO and questionaires from 14 countries which have accepted the irradiation of one or more foods. Though an enormous amount of papers supported the safety of irradiated foods, the true point of these papers is that the reporter could not detect the injurious aspects of irradiated foods and therefore, could not prove they were completely safe.

In this booklet the author intended to uncover the erroneous or tricky logic of the papers which seemingly approve the safety of irradiated foods, if necessary with the help of improved techniques of statistical analysis. The readers should not accept two conflicting conclusions as an expression of agnosticism in science, but consider them as a result of the difference in approach of the two statistical techniques employed.

Most papers on the toxicology of irradiated foods used in this analysis were collected through Index Medicus.

Technical Reports and Documents were obtained from the World Health Organization. The experimental data in Japan were obtained from the Annual Reports on the Results of Research on Peaceful Application of Atomic Energy by the Science and Technology Agency from 1967 to 1981.

The information on the present status of clearance and marketing in each country was obtained by questionaires sent to the Ministry of Health or the Committee on Atomic Energy of each country.

Animal Experiments on the Safety of Irradiated Foods

1. *Irradiated Potatoes*

The country which accepted first the irradiation of potatoes in 1958 was the Soviet Union. Following this the USA, and Canada, in 1964 cleared this technique for the inhibition of the sprouting of potatoes. However, no industrialization of irradiated potatoes was performed in these two countries until now.

Brownell et al (1959), University of Michigan,

reported, in their report on a contract-research for the Army, the result of controlled study on potatoes irradiated at a level of 13-40 krad fed to rats (35 per cent of diet) for two years.

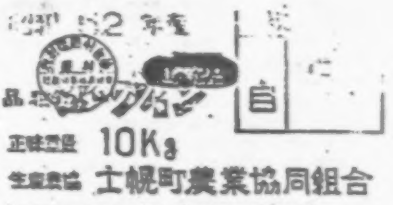
They found an unusually high incidence of a necrotizing artheritis occurring in the first and second generation of the animals. They attributed it to genetic and dietary factors without giving any reason why they did not consider the irradiation of potatoes in the food as a factor. They also observed a slightly high mortality rate of the first generation males fed on irradiated potatoes. Though they considered it to be related to the poor condition of irradiated potatoes, a higher mortality in the second generation males and females, was attributed again to genetic factors.

In 1969 the Joint Committee concluded: In spite of the generally unsatisfactory nature of many of the long-term feeding experiments in animals, the Committee did not find any consistent evidence to suggest that irradiated potatoes are harmful. Thus the irradiation of potatoes at a maximum dose of 15,000 rad for the purpose of inhibiting sprouting was accepted temporarily in the Technical Report No. 459. In 1972, a shocking paper which provocated a violent dispute in the related field was published by Kopylov et al, Institute of Biological Physics USSR. It warned that an acid-extract of potatoes made within a few hours of irradiation with 10,000 rad, when given per os, caused a significant increase in the incidence of dominant lethal mutations in male mice mated with untreated female mice.

Three papers were published criticizing their paper during 1973-1975. At first Levinsky (1972), Bio-research Laboratories in Canada, studied this problem by the request of IFIP and reported negative data. However, according to the personal communication from Kopylov, Levinsky neutralized the extract with NaOH solution before its administration to animals and destroyed the toxin. This neutralization was not described in the report of Levinsky. Osipova et al (1974, 1975), Institute of Nutrition USSR, reported that the toxin was destroyed by heating and storage for 90 days. She also observed the frequency of chromosomal aberrations in the bone marrow of mice after administering extracts of potatoes under various conditions.

Zajtsev et al (1975), Institute of Nutrition USSR, studied the dominant lethal test in mice receiving the extract obtained from potatoes stored 4 months after irradiation and obtained a negative result. Thus, the toxic substance "radiotoxin" found by Kopylov et al in the extract of freshly irradiated potatoes suggests an important feature of irradiated foods that storage for at least 3-4 months is necessary before these foods can be considered safe for human consumption. Brownell, in his experiment in 1959, fed irradiated potatoes to rats after storage for 3 months. However, the Joint Committee did not undertake to demand storage for a definite period before irradiated foods were supplied for animal experiment or human consumption.

In Japan, the Science and Technology Agency started the studies on food irradiation in 1967. In 1971 the result of studies on inhibition of sprouting of potatoes by irradiation was made up to a monograph, and then irradiated potatoes were cleared by the Ministry of Health in 1972. Since then 1.5-3 tons of irradiated potatoes have been supplied for commercial use every year, and have had to encounter consumer's opposition movements everywhere.



A stamp on a carton box of potatoes shipped from an agricultural cooperative association indicates the content as "irradiated potatoes."

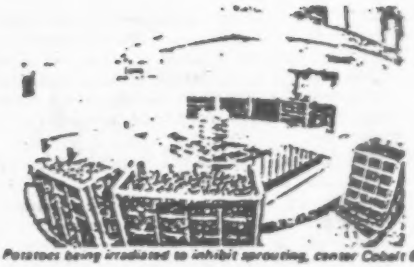
The Joint Committee evaluated these experiments reported by Ikeda et al in the document (1977) and they are summarized as follows:

"(1) All groups fed on potatoes showed somewhat higher mortality than the negative control, but there was no consistent difference between irradiated and non-irradiated diet groups.

(2) Growth was depressed in all male groups given potatoes whether or not irradiated and in females given potatoes irradiated at 30 and 60 krad. There was no significant difference between irradiated and non-irradiated diet groups.

(3) Organ weight showed no consistent treatment-related changes except in the ovaries of rats fed on potatoes treated with 60 krad where a decrease in organ weight was noted. Histopathology and tumor incidence showed no consistent changes related to feeding or irradiated potatoes."

Following such an evaluation of Japanese data in the document, the Joint Committee described this problem in Technical Report No. 604 (1977) as follows: "Long-term studies in two rodent species have shown that the inclusion of irradiated



Potatoes being irradiated to inhibit sprouting, center Cobalt 60.

potatoes in the diet does not induce any adverse effects. One long-term study reported statistically significant changes in ovarian size, but this was not associated with any abnormal histopathological findings.

As this evaluation of the Joint Committee was obviously based on the report from Japan, re-examination of its validity might be the responsibility of Japanese researchers, who are able to obtain the details of the original data.

Further analysis has proved that the irradiation of potatoes influences the ovarian size with a dose of 15,000 rad and that this dose of irradiation might not be considered safe for human consumption. When the original data were inspected thoroughly, increase in the weight of the lung, thyroid gland, spleen, and testes and decrease in the weight of the spleen and suprarenal were found unsystematically everywhere. Such a fact suggests that irradiated potatoes affect a wide range of organs, especially the hormonal regulatory system.

The biphasic variation in the ovarian size without any abnormal histopathological findings will be understood as a secondary effect of the affected hormonal centre.

Even if reproduction studies in animals revealed no abnormalities as a result of ingestion of cooked irradiated potatoes, irradiation of potatoes at a dose of 15,000 rad should not be accepted as safe as it was by the Joint Committee in 1976.

2. *Irradiated Wheat*

Wheat is one of the foods the irradiation of which was cleared very early, in the USA in 1963, and in Canada and in the Soviet Union in 1969, but there has been no industrialization in the USA and Canada, and no information from the Soviet Union. The Joint Committee concluded the unconditional acceptance of wheat and ground wheat product irradiation for the purpose of disinfection at a maximum irradiation dose of 1 KGY (10 kilorad or 10,000 rad) in 1976, following the reevaluation of provisional acceptance at a dose of 0.75 KGY in 1969.

In 1975 two noteworthy papers were published which cast a doubt on the safety of irradiated wheat, i.e. a clinical trial in children and a series of experimental data in animals, from the National Institute of Nutrition in India.

Bhaskaram and Sallvan reported that children receiving 20 g/kg of wheat freshly irradiated at a dose of 75,000 rad developed polyploid cells and certain abnormal cells in an increasing number as the duration of feeding increased, and showed a gradual reversal to the basal level of nil after withdrawal of irradiated wheat. In a marked contrast, none of the children fed unirradiated wheat showed polyploids and abnormal cells were of a significantly decreased number. Though the biological significance of polyploidy is not clear, its association with malignancy makes it imperative that the wholesomeness of irradiated wheat for human consumption should be very carefully assessed, they said.

Vijayalaxmi reported in a series of reports a higher incidence of breaks and deletion in the bone-marrow of rats fed on wheat irradiated at a dose of 75,000 rad, an increase of polyploid cells in the bone-marrow depending on the duration of feeding on irradiated wheat, an increase in dominant lethality in rats after feeding on irradiated wheat, a reduction in number of germ cells in the testes of rats, an increase of chromosomal aberrations in peripheral lymphocytes and endoreduplicated cells in leucocytes of monkeys fed on irradiated wheat and that these effects were dependent on the duration of storage after irradiation.

With regard to the paper of Bhaskaram and Sadasivan, the Joint Committee stated that no increase in polyploidy was seen when wheat stored for 12 weeks after irradiation was used and no problems are likely to arise in practice, since irradiated wheat is usually stored for longer than 12 weeks. However, rats fed on wheat stored 12 weeks after irradiation for 6 weeks showed still 0.6 per cent of polyploid cells and the authors concluded that wheat must be stored for a period "beyond" 12 weeks. There is no mention of the duration of storage before it can be considered safe for human consumption.

Two papers which negated the chromosome injury due to irradiated wheat were published from the Bhabha Atomic Research Centre in India in 1976 and 1977. Contrary to their conclusion, a significant increase of polyploid cells in the bone-marrow of rats was revealed in the data of George et al. Though in the group (protein 16 per cent plus wheat 75 per cent) and the group (P 11-12 + W 20) a tendency of increase in polyploid

cells in the test animals and in the first experiment of the group (P 11-12 + W 90) a significant increase were detected, in the second experiment of the last group such a tendency was not detected, because of a higher incidence in the control group than the others. Therefore, the tendency of increase of polyploid cells in the bone-marrow of rats fed on irradiated wheat (in test animals) might be difficult to negate.

Chauhan's paper in 1977 shows a tendency of increase of living implants and decrease of dead implants per female in rats fed wheat irradiated at 75 krad and mixed in the diet 16 per cent.

For the sake of safety approval for human consumption the insufficiency of knowledge on the pathogenicity of polyploidy at present also should not justify the negation of prominent evidence of chromosome injury like polyploidy.

Ikeda et al, the National Institute of Health of Japan, published a report on the effects of irradiated wheat in three generations of rats in 1980. In spite of their conclusion that no influence due to irradiation was detected, the weight of the ovarium (per 100 gr of body weight) showed a significant decrease in the first and in the second generation, but an increase in the third generation. The constancy of such a biphasic response in the progress of a generation must be reconfirmed in the future. Meanwhile, we should not accept the conclusion that there exists no health hazard resulting from the consumption of irradiated wheat and ground wheat products as the Joint Committee concluded in 1976.

3. *Irradiated Onions*

In 1980 of the Joint Committee concluded the unconditional acceptance of irradiation of onions for the purpose of inhibiting sprouting, with a maximum dose of 15,000 rad. This followed the conditional acceptance in 1976. Tobe et al in Japan reported the experiment on rats and mice fed on irradiated onions. The earlier occurrence of death and higher death rate was observed in male rats fed on onions irradiated at a dose of 15,000 and 30,000 rad, but not in females.

Secondly, as done on irradiated potatoes, the time course of relative values of means of the ovaries to those of unirradiated control was obtained for each group with specific doses of irradiation. The Joint Committee summarized the toxicological data: "Long-term studies on mice and rats revealed no excessive mortality. The statistically significant changes in the weights of the ovaries and testes observed when irradiated onions were fed to mice were not associated with abnormal histopathological changes or deleterious effects on reproduction. The changes in organ weights were therefore not regarded as being of significant harm to human health." The result of analysis of Japanese data as stated above could not support the acceptance of onions irradiated not only at a dose of 15,000 rad accepted by the Joint Committee but also of 7,500 rad.

4. *Irradiated Rice*

The Joint Committee concluded the unconditional acceptance of irradition of rice at a dose of 100,000 rad in 1980, following the conditional acceptance in 1976. Tobe et al in Japan (1980) reported the short-term studies on monkeys. Relative organ weights of the thyroid gland, heart and lung of animals fed on irradiated rice diet were significantly lower than those of monkeys fed on unirradiated rice. This decrease in several organs was excluded from the evaluation of the Joint Committee, because of the lower body weight in the group of monkeys fed on unirradiated rice than that of the control group fed on the standard diet.

The composition of the rice diet was obtained by the modification of that of a standard diet as follows: addition of powdered brown rice 40 per cent, reduction of flour from 33 per cent to 18 per cent, elimination of 10 per cent corn, 10 per cent of barley powder and 5 per cent of fat free rice bran. As the preliminary study was not performed so as to prove the nutritional equivalency of the two kinds of diet, the difference in body weight between the group of monkeys fed on rice diet and those fed on a standard diet might be due to the difference in nutritional efficiency of the two diets. The above-cited analysis reveals that there is no reason to consider the body weight of monkeys fed on unirradiated rice diet abnormally lowered by any accident and that there might be no problem in comparison of relative organ weight between monkeys fed on an irradiated rice diet and those fed on an unirradiated rice diet (for evaluation of the effect of irradiated rice). The most noteworthy changes in relative organ weight are the tendency of increase in the pituitary gland and the significant decrease in the thyroid gland and the

tendency of decrease in the testes. The significant decrease in the weight of the heart and the lungs may be the secondary effect of the hormonal disturbances.

The following problem on irradiated rice is its tumor inducing feature. Tobe et al reported the result of experiments in rats and mice fed on irradiated rice for 2 years. As they give the number of animals in the table, the incidence of tumors for each group of animals fed on rice irradiated at zero, 5 and 10 krad is obtainable.

The difference between unirradiated and irradiated diet groups seems to be clear and dose-related especially in females. The result of this analysis contradicts the conclusion of the Joint Committee that the ingestion of irradiated rice caused no adverse effects on the test animals and does not support the validity of unconditional acceptance of rice irradiated at an average dose of up to 100,000 rad.

5. Other related topics and summary

After the Second World War ionizing irradiation by cobalt 60 for preservation had been performed fervently by the US Army and the British Atomic Energy Commission, until the Food and Drug Administration of the USA, alarmed in 1969 at the safety of irradiated food after the accumulation of experimental evidence invited the US Army to withdraw its application for permission to go ahead with the irradiation of canned ham or it would be refused.

The Food and Drug Administration insisted that the feeding of irradiated bacon to rats had been followed by marked reductions of the viability of the offspring of the animals, sometimes 23 percent less than the numbers born to the control animals.

The injurious effect of irradiated ham was also supported by the evidence of reductions of red cell counts and body weight and of an increase of mortality in mice and rats fed on irradiated pork. Less striking tendencies of a reduction of body weight were observed in experiments with dogs. In a tentative way the elevated incidence of pituitary tumor was noted in a group of rats fed on irradiated bacon.

The number of countries which had plans for food irradiation amounted to 76 in 1969, but it decrease to 19 in 1978, after 10 years. After this event, promotion of food irradiation was shifted to Europe, where the following International Organizations acted as active promoters of this technique: Food and Agricultural Organization (FAO), International Atomic Energy Agency (IAEA) and World Health Organization (WHO). A Joint FAO/IAEA/WHO Expert Committee on the wholesomeness of irradiated food was held in 1969, 1976 and 1980. In the meeting the Committee discussed the principles of evaluation of wholesomeness and determined recommended doses of irradiation for particular foods from the view point of toxicology.

Theoretical approval of the safety of irradiation at 1,000,000 rad

The Joint Committee held in Geneva in 1980 concluded that the irradiation of any food commodity up to an overall average dose of 1,000,000 rad presented no toxicological hazard, hence, toxicological testing of foods so treated was no longer required. Concerning this approval, the Joint Committee stated that this development was derived logically from the assessment of the wholesomeness of irradiated food adopted in 1976 by the previous Committee which are as follows:

a) Radiation chemistry studies have now shown that the radiolytic products of major food components are identical, regardless of the food from which they are derived; most of these radiolytic products were the same as could be identified in foods treated by other accepted types of processing. Knowledge of the nature and concentration of these radiolytic products indicated that there was no evidence of toxicological hazard.

b) All the toxicological studies on laboratory animals fed on a variety of irradiated foods and also the practice of maintaining immunologically incompetent patients on irradiated diets have produced no evidence of adverse effects resulting from irradiation. With regard to the conclusion derived from radiation chemical studies, caution must be exercised to the fact that proteins, carbohydrates and lipids in foods are actually to be presented as a complex system, whereas radiochemical studies were performed on each purified nutritional constituent. There is no proof of the fact that the sum of the properties of the particular elements represents that of a whole biological system. Interactions between constituents should be taken into consideration.

In 1977 a book entitled "Radiation Chemistry of Major Food Components" was published by P.S. Elias and A.J. Cohen (ED). Dr. Elias, the President of IFIP, stated in the introduction that "the available data on the chemical structure of radiolytic products in food and any low concentrations of them which have been detected suggest the general conclusion that the health hazard they might represent is negligible." Prior to criticizing his conclusion in this book, we shall study what actually happens to foods when they are irradiated.

The chemical nature of food irradiation is expressed by the term "ionizing irradiation". Chem-

...ical substances produced in foods by irradiation are derived from two different mechanisms which have a complex correlation with each other. One is a series of reactions due to several ionized radicals produced by direct action of irradiation to water which provides a significant component of most foods, that is free hydroxy radicals (OH), hydrogen atoms (H), hydrated electron and so on. The other is a series of organic radicals produced by direct action of irradiation on the components of food and by indirect reaction through OH, H and hydrated electron to them. Dissolved oxygen from the air promotes the decomposition of water and therefore the dissolved oxygen in the food will be consumed very quickly.

Hydroxy radicals (HO) abstract hydrogen atoms from carbon-hydrogen bonds in aliphatic compounds such as alcohols, carbohydrates, carboxylic acids, esters, aldehydes, ketones, amino acids etc. In all cases the product of the reaction is an organic free radical. The hydrated electron is the second major reactive species in the irradiated aqueous system. Its reaction is more selective than hydroxy radicals. They attach quite rapidly to compounds such as most aromatic compounds, carboxylic acids, aldehydes, ketones, thiols and disulfides. With proteins they attach to histidine, cysteine and cystin residues, but do not react significantly with the main components. They react with minor components such as vitamins, pigments, etc. Hydrogen atoms (H) are produced in a relatively low yield on the irradiation of water, but may also be produced through the direct excitation or ionization of certain organic compounds. They can attach to aromatic and olefinic compounds and also abstract hydrogen atoms from carbon-hydrogen bonds in aliphatic compounds like alcohol, carbohydrates and probably aldehydes. They abstract hydrogen atoms from thiol, but can also attach rapidly to disulphides, splitting the S-S bond into -S and HS-. With proteins their predominant reaction is thought to be that directed at sulphur-containing and aromatic amino acids.

Secondly organic radicals are formed by indirect action through OH, eH and H as well as by direct action. Organic free radicals may abstract hydrogen atoms from organic molecules, resulting in the reconstitution of the original compounds. Some radicals may decompose, as seen in carbohydrates. Organic radicals are able to attach themselves to double bonds, but the rate is normally low.

Organic radicals are usually of reducing capability and may reduce minor constituents. They react with oxygen and produce a peroxide radical. This reaction may give rise to a chain oxidation resembling autoxydation. The reaction is especially marked with unsaturated fats. The excited states of some organic molecules may be sufficiently long-lived for them to transfer energy to others – there is no evidence of this in water. These radical species may finally disappear by reacting with each other in complex chemical reactions. Among these radiochemical studies it might be noteworthy that in dried, irradiated products, such as dried cells and starch, radiolytic products including free radicals can be detected long after the time of irradiation (Ehrenberg, 1957). Standing on these principles of radiochemical reactions by particular ionized radicals stated by A.J. Swallow, we shall reexamine the critical conclusion by four reviewers on major food components:

(1) Protein (W.M. Urbain): Although much valuable information is available on the radiation chemistry of pure amino acids and proteins, care is needed in extrapolating such findings to the irradiation of proteins in food. There may be interaction among the radiolytic products of all components, and so on.

(2) Lipids (W.W. Nawar): Caution should be exercised in extrapolating the results of model systems and natural fats to evaluate the decomposition products in heated or which must be taken into account. This has yet to be investigated and more studies are needed on radiolytic polymerization, effects on phospholipids and polyunsaturated fatty acids and interaction with other food nutrients.

(3) Carbohydrate (J-H. Douphin): Although it is easy to distinguish between the solid state and solution in the case of pure sugars, it is much less so (so far) with food stuffs and vegetables. For these reasons, extrapolation from pure sugars to foodstuffs will always be difficult.

(4) Vitamins (P.P. Tolstoch): – relatively few studies have been involved in identifying the degradation products formed on irradiation. It is generally recognized that Vitamin E is the most radiation-sensitive of the fatsoluble vitamins, whilst vitamin B is the most radiolabile of the water-soluble vitamins. In cases where no data is available on the radiation stability of a given compound in a food product an attempt may be made to extrapolate the data obtained from studies with model systems to the natural food system. Any conclusions so drawn should however, be carefully interpreted.

The above-cited parts of conclusions to each chapter seemingly support the foreword by P. Belligoni and Prof J.F. Diehl: "While an impressive amount of information on the radiation chemistry of pure substances is available, attempts to extrapolate this information, so as to permit prediction of radiation-induced changes in complex foodstuffs, are based on some common assumptions. We still know too little about the

thereof influences of the food constituents when they are irradiated simultaneously."

As no decisive progress was reported after the publication of this book on radiation chemistry, the conclusion of the Joint FAO/IAEA/WHO that the irradiation of any food commodity up to an overall average dose of 10 kGy (1,000,000 rad) presents no toxicological hazard, must be based on some uncertain assumption and said to be unworthy of the authority and responsibility of the International Organizations.

As stated above, toxicological studies on potatoes, onions, wheat and rice revealed the danger of food irradiated at a dose as small as 1/10, 1/100 of 10 kGy in experimental animals and sometimes in malnourished (human) children. These facts proved the unreliability of the approval of the Joint Committee on the safety of irradiation at a dose of 10 kGy not only theoretically, but also experimentally. The present author would like to stress the fundamental fact that toxicological studies performed on the whole body of animals could never be sufficiently substituted by the summation of chemical, analytical or in vitro studies.

Present status of clearances and marketing in the world

A short of questionnaires on the present status of clearance and marketing of irradiated foods was sent in 1981 to the Ministry of Health or the Committee on Atomic Energy of 22 countries which were listed in the table titled "Dates of Food Clearance in 6 country for 6 Given Food Item or Group of Related Products" in Food Irradiation News Letter published by IAEA in 1983. When the answer was not obtained in 1983, a cooperation of the Consulate of each country in Tokyo was requested.

The summary of the answer from each country is as follows:

Australia: The Food Administration Section answered that Australia has not yet actually approved the irradiation of any food products. Consideration was given to the irradiation of frozen shrimps, but this was not approved by the National Health and Medical Research, as the basic approach for the irradiation of shrimps did not meet the Microbiological Standard for Precooked Frozen Prawns. By such a statement Australia rejected the clearance for frozen shrimp issued in IAEA's chart.

Belgium: The National Institute of Radioelements confirmed the approval of irradiated potatoes and strawberries in 1980 as listed in the chart of IAEA, but these were valid for a period of 10 years. Though missed in the chart, irradiated onions, garlic, shallots, paprika and prawns were approved in 1980 for provisional consumers. Applications for further 6 approvals have been presented to the government: chicken, shrimps, enzymes, pure water, spices in general and dried vegetables. However, no irradiated foods have so far been sold in the market.

Canada: The Food Directorate confirmed the clearance of irradiation for potatoes in 1964 and for onions in 1962 for the purpose of antisprouting and that of wheat, flour and whole wheat flour for disinfection in 1969. However there were no cobalt-60 gamma irradiation in commercial use in the food industry in July, 1983. By this answer Canada negated the clearance of cod and haddock fillets and wholepotato meal in IAEA's chart and canceled the yields of clearance for potatoes from 1968 to 1964.

Czechoslovakia: The National Committee for Fe(II)/UN answered that they did not use irradiated food for marketing purposes, only for experimental use in their research institutes.

Chile: The Ministry of Health confirmed the clearance of irradiation for potatoes in 1970 as the list of IAEA, for strawberries and dried fruits in 1979, for fibers in potatoes in 1980, for onions and prawns in 1981.

Denmark: The National Food Institute answered that foods treated with ionizing radiation should be designated as such on the label of the retail package of the foodstuffs. The Bodies of persons found that the consumers would then not buy the food, and this was the reason that the authorization was never utilized for irradiation.

Israel: The Atomic Energy Commission confirmed the clearance in the list of IAEA and added that they hope to receive clearance for poultry meat and spices during 1983.

France: The Department of General Prevention and the Government confirmed that irradiation of potatoes was cleared in 1972 for five years only. However, now it is not authorized because the process is not used in France. Irradiation of onions and shallots was cleared in 1977 and for treatment was marketed after that for five years only. The clearance of irradiation of garlic in 1977 in the list of IAEA was not confirmed by the Department. The Department delivered that the irradiated spices will be authorized in the near future.

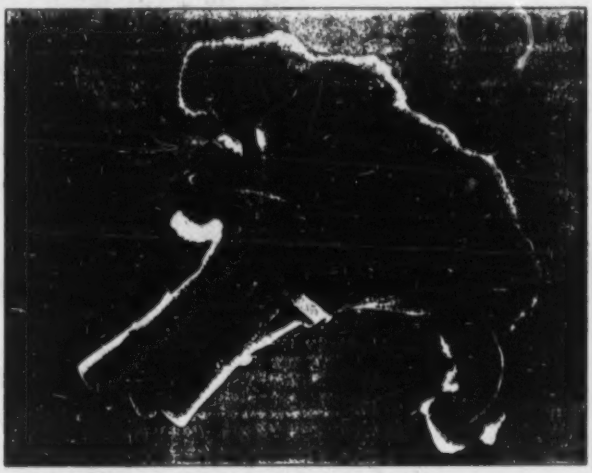
West Germany: The Ministry of Youth, Family and Health answered that in West Germany the ionizing irradiation of food and the circulation of foods that treated were forbidden by law. The allowed dose of irradiation of food should not exceed 10 rad. At present there is no possibility of loosening the law. Further, the Federal Research Centre for Nutrition answered that they

HEALTH

BY ANNE WITTE GARLAND

THE NEWEST PROBLEM ON THE FOOD FRONT

Warning: You Can't See It, You Can't Taste It, but You May Eat It



IF YOU'RE CONCERNED ABOUT pesticides, dyes, preservatives, and other forms of adulteration of your food, here's something new to worry about: in the near future, that slice of pork or fresh-looking vegetable or piece of fruit you bite into may be treated with *radiation*. The federal government and part of the food industry have apparently embarked on a campaign to sanction and promote food irradiation: the Food and Drug Administration (FDA) approved pork irradiation this summer, and is expected to give the go-ahead to irradiating fruit and vegetables by the end of the year. Although irradiation enthusiasts cite a long list of benefits of irradiating food, critics say that it's far from being proved safe, and that in allowing it, the FDA is disregarding its own usual testing requirements.

One fear you *needn't* have about food irradiation is that the food itself will be radioactive. It won't be—just as your teeth aren't radioactive after they've been X-rayed. But while radioactivity of the food isn't a problem, there are a number of other serious concerns about treating food with radiation, including possibly harmful changes in the food, and significant new radiation threats to the environment, food processing workers, and the public.

The FDA, which regulates food additives and is required by law to determine that they're safe before allowing their use, dismisses the concerns—at least for doses up to certain levels. Last year, following the usual procedure for issuing new agency-initiated regulations, the FDA published a "proposed" regulation to allow radiation treatment of fresh fruits and vegetables to kill insects and retard spoilage (it said that it would later consider allowing other uses requiring higher radiation doses). The agency then received public comments on its proposal, and is expected to issue approval in the form of a final regulation before the end of this year.

Meanwhile, in late July the FDA unexpectedly approved irradiation of pork to kill *trichinella spiralis*, the parasite that causes trichinosis. Since that regulation originated as a petition to the agency from an outside company, the FDA didn't have to publish a proposed regulation and solicit public comments; instead, the approval simply went into effect, and critics had 30 days in which to voice objections. Several groups did, arguing that not enough is known about irradiated food to prove that it's safe and that the FDA didn't adequately consider the environmental implications of irradiation. (In fact, critics say, it appears that the FDA rushed the pork irradiation approval through in order to avoid its own new rule that went into effect three days later, one that clearly requires an "environmental assessment" in such cases.)

THE IMPRESSIVE CLAIMS

In the irradiation treatment process, food in containers (metal boxes, crates, or even airtight packaging) is placed on conveyor belts and guided into closed chambers, where it is exposed to radiation at specific doses. The radiation can be in the form of gamma waves from a radioactive substance like cobalt-60 or cesium 137, or X rays or electrons generated by machines; the dose required depends on the food and the purpose for which it's being irradiated.

The vision that irradiation enthusiasts in industry and government paint of what the process can do is certainly appealing, with purported benefits ranging from delaying rotting of strawberries to helping alleviate world hunger. As a pesticide, they say, irradiation could be used in the place of dangerous chemicals like ethylene dibromide (EDB), a fumigant that the Environmental Protection Agency banned in 1984 since it's a known carcinogen. As a preservative, irradiation could be substituted for things like the potentially cancer-causing nitrates and nitrites used in cured meats. Irradiation of pork and poultry can kill the parasite that causes trichinosis, and at high enough doses, also kills bacteria like salmonella. At very high doses, it could completely sterilize food, eliminating the need for refrigeration at all. (It's not irradiation that allows European consumers to buy unrefrigerated milk, however; that's a different sterilization process. Irradiation causes odors in dairy products, making them inappropriate candidates for the treatment.) Finally, because of its ability to prevent spoilage, irradiation advocates say, the process could cut food losses and help combat world hunger.

The idea of irradiating food for at least some of these purposes has been tossed around for decades—especially

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by the U.S. Army, and as part of President Eisenhower's "Atoms for Peace" program (which spawned nuclear energy as well). The Army began in the early 1950s to look into the treatment as a way of preserving food for field troops, and from 1953 to 1978 spent $51 million on testing meant to prove the safety of irradiating certain meats. By last year about $80 million had been spent by government and industry on food irradiation research, according to Health and Human Services (HHS) Secretary Margaret Heckler, an irradiation advocate (and an important one, since the FDA comes under her department), whose former Congressional district encompassed Natick, Massachusetts, the site of much of the research.

In spite of the early high hopes, food irradiation hasn't caught on—*yet*. In the 1960s the FDA approved limited radiation treatment of wheat to disinfest it (kill insects) and irradiation of potatoes to inhibit sprouting, but because they aren't economical, these applications haven't been used commercially. In 1963, the FDA approved irradiation to preserve bacon, but later banned this use when it learned of "deficiencies" in the research data collected for the Army on which the FDA had based approval. In 1981, the FDA offered the fruit industry in California the opportunity to use irradiation experimentally to help control fruit flies, but no firm could show that it would be able to meet safety conditions required for the process. Two years ago the FDA approved irradiation for disinfesting certain spices. Even this application is uncommon, though, and right now the only irradiated food reaching U.S. consumers may be some spices on certain foods, such as frozen pizzas. (The FDA regulation likely to go into effect this year allows increased doses of radiation for spice treatment in addition to permitting produce irradiation.)

The experience with irradiation in other countries—where food safety regulations aren't necessarily as stringent as in the United States—has been limited as well. Although proponents point out that food irradiation is approved in some form in about 20 countries, in most the approval is restricted to just a few uses, and the process is employed widely only in South Africa, the Netherlands, and Japan.

There may be several reasons the U.S. government and industry have moved so slowly with the technology, including doubts about whether it's economical and whether the public will accept it. But probably the most serious roadblock has been the difficulty in proving that irradiation is safe. In fact, despite all the money that's been spent on research on irradiation, and despite the FDA's current claims, safety is still very much in question—which is why it's alarming to see that the government and some industry groups seem so bent on going ahead with it now.

SAFETY CONCERNS

Harry Mussman, vice president of the National Food Processors Association and chair of a recently formed industry group to promote irradiation, the Coalition for Food Irradiation, has remarked that if we hadn't accepted cooking of food and it were being proposed today, we'd be worried about that process, too. Sanford Miller, director of the FDA's Center for Food Safety and Applied Nutrition, chalks up fears about food irradiation to what he sees as "a kind of 'technical neo-phobia,'" and claims that people might be less worried if they knew, for instance, that irradiation has been used for years to sterilize hospital equipment. (Of course, we don't *eat* hospital equipment. And while irradiation is also used to treat food for astronauts on space flights, it can be argued that astronauts take any number of risks that others of us might choose not to take.) The most attractive claim about food irradiation, made by the Coalition for Food Irradiation and others, is that it can be used as a substitute for dangerous fumigants and preservatives—but unless it's safer than what it's replacing, that claim is worthless.

There may actually be very good cause to be concerned about the prospect of routine irradiation treatment of food. Here are some of the problems and potential problems that have been raised:

- *Not enough is known about chemical changes in food when it's irradiated.* When radiation hits food, most of it passes straight through without changing it. The rays that don't pass through create a kind of chemical havoc by setting the food's own electrons in action. These electrons start bouncing off one another, killing insects, destroying bacteria that cause spoilage, and slowing cellular growth (thereby slowing ripening)—but also breaking chemical bonds and creating new chemical substances, called "radiolytic products." Some of these products are identical to naturally occurring substances; others, though, are completely new—and because so little is known about these "unique radiolytic products" (URPs) and their health effects, they're a cause of serious concern to some scientists and health advocates.

Irradiation critics like the Public Citizen Health Research Group in Washington, D.C., contend that the only way to prove that these substances are not toxic or carcinogenic is through adequate traditional long-term testing—involving feeding the URPs found in irradiation-treated food to lab animals at higher doses than are being proposed for human food consumption. (High doses are standard in testing and are necessary to detect any problems, says Health Research Group attorney Allen Greenberg, because only a small number of animals would be tested, while large human populations would be affected; and because animals would be fed the treated food for only short periods, compared to humans' lifetimes of exposure.)

Current FDA policy requires this kind of testing for all other chemical substances like food additives and workplace chemicals. According to the Health Research Group, though, the studies that have been done to date on food irradiation have utterly failed to show safety. Studies sponsored by the U.S. Department of Agriculture, using food exposed to high doses of radiation, found problems like testicular tumors or damage, lower survival rates of animals, and decreased offspring; a number of older Army-sponsored studies using lower radiation levels had to be rejected by the FDA because they were inadequate and in some cases fraudulent.

So, faced with the difficulty of proving the safety of food irradiation through the usual testing, the FDA apparently decided to reverse its own testing policy. Last February when it announced its preliminary proposal to allow produce irradiation, it declared that it had already been satisfactorily determined that irradiation at the levels it was proposing was safe. But, the Health Research Group argues, that determination isn't based on tests (in other words, on actual scientific evidence of safety), but on *estimates* of the amount of radiolytical products formed in food exposed to doses the FDA is proposing, and on the unsupported conclusion that such food is safe.

- *Irradiated food could be less nutritious, or downright unsafe, for other reasons as well.* Irradiation conceivably could destroy certain organisms in food that cause smell or other usual signs of spoilage without completely killing off the harmful organisms causing the spoilage itself. Thus, consumers could buy unhealthy food that looked and smelled perfectly healthy. In addition, some research indicates that irradiation can af-

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fect fats and amino acids, and to a degree, destroy vitamins such as A, B, C, and E. (The FDA rejects both of these concerns at the irradiation levels it is proposing, and says it will look into them further before allowing higher levels.) Another concern of some consumer groups is that irradiation of food could increase the production of aflatoxins, naturally occurring carcinogens that are produced by some types of fungus and are especially prevalent in grain. The Environmental Protection Agency considers aflatoxins to be about a thousand times more carcinogenic than EDB.

● *Food irradiation could pose other threats to the public and the environment, as well as to workers in processing plants.* Groups like the Washington, D.C.-based Environmental Policy Institute and Health and Energy Institute worry that widespread use of food irradiation would dramatically increase the amount of radioactive materials being used and transported. The amount of radiation that would go in and out of one typical food irradiation plant every five years, they argue, would be five times the total volume of low-level nuclear wastes produced in the United States by *all* sources in 1981. Nuclear materials transportation is already enough of a concern that many states and localities have attempted to ban it altogether on their roads and highways. There will also be the residually radioactive wastes to dispose of, at a time when nuclear *power* wastes are already a recognized serious problem for which no acceptable solution has been found.

In addition, although irradiation advocates argue that it will reduce workers' exposure to dangerous chemicals, workers at irradiation facilities could face even more serious dangers from routine radiation leaks or accidental exposures. And the assurance by the FDA that facilities would be regulated by the Nuclear Regulatory Commission and the Occupational Safety and Health Administration instills little confidence in nuclear critics. These critics are also concerned about plans that they believe are going forward for building irradiation facilities subsidized by the U.S. Agency for International Development in several Third World countries, where there is even less assurance of worker and public safety.

● *Food irradiation might not be necessary as a substitute for EDB, or useful in solving world food shortages.* One of the most common arguments for using irradiation is to replace EDB disinfestation of fruit and wheat. As the Health Research Group and Environmental Policy Institute point out, though, there are other, safer ways—including exposing fruit to heat and then cold storage, or fruit-fly control programs that involve monitoring the fly population and managing it by releasing sterile male insects. For disinfesting stored grain, carbon dioxide, microwave, or infrared treatments are alternatives to EDB and irradiation that don't share either's drawbacks. And since food irradiation will involve building major new facilities, it's unlikely that it would be more economical than the other alternatives.

As to the claim—made by HHS Secretary Margaret Heckler and others—that food irradiation could help solve the world's food shortage and hunger problems, Linda Pim, a science writer who researched irradiation for Pollution Probe in Toronto, calls that solution a "technological fix" that should be recognized as unworkable, since hunger is "as much a political, cultural, and socioeconomic problem as it is a scientific and technological one." (Grain spoils on Ethiopian docks because of inadequate distribution facilities, for instance; irradiation is not a solution to that problem.)

Food industry support for irradiation is by no means monolithic. Citrus growers don't like it, since irradiated fruit can bruise easily and develop black spots on its skin. Retailers and some food processors worry about its cost, and whether consumers will shun irradiated foods. The real force promoting food irradiation, says the Environmental Policy Institute's Robert Alvarez, is still the military, as well as the irradiators themselves. The government is currently planning to build three demonstration food irradiation facilities—including one near San Francisco, California, and a mobile irradiator—funding for which is coming, not from sources like the Department of Agriculture, or HHS, but from the nuclear weapons budget of the Energy Department (which is also offering wastes from nuclear weapons production for use in food irradiation at a significantly lower cost than normal for other radiation sources).

CONSUMER ACTION

If food irradiation is so bad, or at least not so good as to warrant taking the risks involved without further proof of safety, then what can consumers do? One obvious step is to avoid irradiated products. Current law requires labeling of food additives, and although the FDA's proposed regulation last year didn't include a retail labeling requirement for irradiated foods, it has indicated that its final regulation this year may. (If labeling *isn't* required, the only way to discover whether produce has been irradiated will be to ask at the supermarket or fruit stand.)

Here are some other possible steps:

● Pressure grocery stores and produce stands to refuse to stock food that's been irradiated. Talk to store managers, organize local boycotts, and go after chain stores' parent corporations.

● Ask state legislators and governors to ban the sale of irradiated foods in your state, as well as the construction or operation of food irradiation facilities.

● Urge Congressional representatives to oppose the "Federal Food Irradiation Development and Control Act of 1985" (HR 696 and S 288). This legislation, introduced by Representative Sid Morrison and Senator Slade Gorton, both Republicans from Washington State, would, among other things, do away with any requirement of labeling of irradiated foods, provide for a federal promotional campaign for public acceptance of food irradiation, and prohibit state and local governments from requiring labeling or banning the sale of irradiated foods.

Anne Witte Garland is a writer and editor based in New York.

Health *Shortakes*

Cultivating the Healthy Ego

Any woman who fears she's losing track of her unique identity in an endless round of caretaking duties will find help in *From Fear to Freedom: A Woman's Handbook for High Self-Esteem*, by Darlene Deer Truchses (New Option Publishing, 1939 Park Avenue, Denver, Colorado 80218; $9.95). Truchses assists the reader in a personal inventory and gives her a short course in feminism in everyday life.

Final Rights

If you want to ensure, in the event of catastrophic illness or injury, that your life is not prolonged by extraordinary means, you can obtain the legal documents appropriate for your state free from the Society for the Right To Die. The society has publications for lawyers, health professionals, and the layperson about the questions involved in death with dignity. A tax-deductible contribution of $10 entitles you to membership and a newsletter. Contact: Society for the Right To Die, 250 West 57 Street, New York, New York 10107.

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The Safety Of Food Irradiation

by Colum DeLaney

The food industry has come up with a hot solution to the twin problems of nuclear waste disposal and keeping food fresh and pest-free. If the industry has its way, Cobalt 60 and Cesium 137 from defunct nuclear power plants (shut down for safety reasons), as well as leftover nuclear wastes from nuclear weapons manufacture will be used to irradiate up

If the [food] industry has its way . . . leftover nuclear wastes from nuclear weapons manufacture will be used to irradiate up to half the food you eat.

to half the food you eat.

Food irradiation is not a new idea—it began in the 50's as part of Eisenhower's "Atoms for Peace" program. Used recently it has been used sparingly, mostly on spices or on potatoes intended for export to Japan. The banning of the dangerous pesticide EDB last year, however, made food processors turn to the idea of preserving and sterilizing food with gamma rays.

FOOD IRRADIATION: THE PROCESS

The process involves moving food on a conveyor belt into a concrete bunker, where a source such of Cobalt 60 or Cesium 137 lies stored in a pool of water. The source rack is raised into the radiation chamber, and as the food passes by, a dosage dose equal and the food is bombarded with gamma rays. While many foods will receive doses of up to 100,000 rads, the dose can range as high as 4 million rads, depending on the type of food. (A chest x-ray, in comparison, is less than one fourth of one rad. The amount of single dose of radiation that would kill one out of two humans exposed to it is 300 rads.)

At lower levels of exposure, insects found on harvested fruit are killed or sterilized. Garlic, potatoes, onions and carrots stop sprouting. Fruits can be delayed from ripening. At higher doses, the shelf life of fresh foods is lengthened, as the microbes responsible for food spoiling are destroyed by the radiation. Fish could be refrigerated after irradiation and shipped all over the country, making its freshness for weeks on end.

High enough doses delivered to meat and poultry render them virtually sterile—ready if hermetically sealed, they can keep indefinitely. One proponent of food irradiation likes to show his visitors a cooked raw steak, appetizing and edible looking, which he then reveals has sat on his shelf, at room temperature, for years.

While the process of irradiating food sounds simple and straightforward, there are many factors influencing it, as well as many problems associated with it. The effects of irradiating food depend not only on the dose of radiation delivered, but on many other variables involving the type of food, its moisture at harvest, how it is handled, etc. According to Louis Rankin, formerly of USDA Agricultural Research Service, there is a very delicate balance between the doses that can safely preserve a food and the doses that can damage the product over its marketing life or sterilize it, rendering it virtually inedible.

Delivering too high a dose to fruits or vegetables, due to dose variables affecting the dose, can cause visible changes in its color by darkening it both inside and out, in its texture by increasing its mushiness, and in its taste. But more alarming is the processing that are going on within the food itself during irradiation that are not so noticeable.

In irradiating food, all experts agree, does not render it radioactive, any more than receiving dental X-rays leaves your teeth emitting radioactivity. But undesirable changes in the molecules making up the food do occur, even though the food itself is not made radioactive.

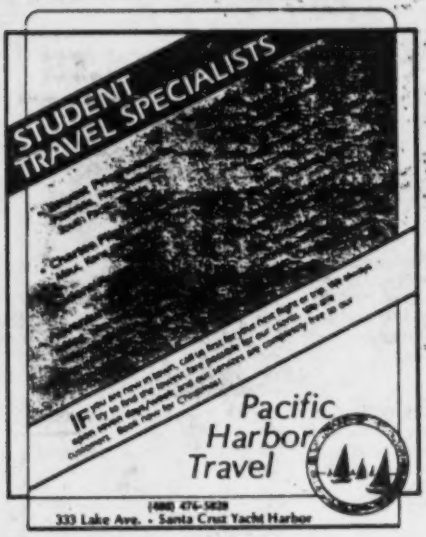
The structure of foods is altered when incoming gamma rays kick electrons out of their orbits around the atoms, and these atoms then become electrically charged ions. The result often produces damage to parts of the living cell. During this ionization, highly reactive unstable molecules called free radicals are produced and cause damaging events in cells. Free radical formation happens most easily in water—and the water content in fresh commodities is 65–90%. Cell death and damage to genetic material in cells follows.

The damage that takes place in food can be precisely measured in experiments. In whole fruits and vegetables an unmistakable increase in ethylene given off is a common response to physical injury and can be measured by gas chromatography—and this response follows in plants that have been irradiated, with the increase being directly related to dose.

HAZARDS FOUND IN FOOD IRRADIATION

What does this damage mean in terms of the food itself? To hear proponents of food irradiation tell it, there is no danger at all associated with these structural changes. "Thirty years of research have shown that the proposed levels of irradiation are safe," says Margaret Heckler, Health and Human Services Secretary Heckler also pointed out that food irradiation has been used in 28 countries.

John Gofman, author of *Radiation and Human Health* and longtime anti-nuclear power activist, replied to Heckler's claim, saying, "If Margaret Heckler says irradiation is safe then Margaret Heckler is lying . . . if there are 28 countries using this process, that just proves there are irresponsible people all over the world." Because radiation-induced diseases like cancer can take decades to develop, Gofman means that efforts to determine the long-term safety of irradiating foods would require a survey of some 200,000 administered over a period of 50 or more years. Gofman calls it "a fraud" to tell the public we know that irradiated foods are safe to eat. We really don't know how radiation will affect food in the long term, or how it will affect the people who eat it.



Introducing

What Does This

by Terry Tamminen

This "Radura" could be the friendly green symbol to look for when you want food products which have the added benefit of being "gamma processed." In other words, it would signify foods which have been irradiated—a process of bombarding foods with ionizing radiation to rid them of insects and pests and prevent spoilage.

Why not tell it like it is and mark the foods "treated with ionizing radiation," as currently required by law? Well, in the words of Marilyn Young, of the Consumers' Association of Canada, "A label is to give specific information. The information we want conveyed is that this food has been irradiated, but we don't want to use that term . . . It lends the average person to believe that food could be radioactive."

Ms. Young maintains, however, that people who have their own reasons, whenever they may be, for wanting to avoid "treated" (read: irradiated) food are entitled to a label which will alert them. The Radura could satisfy these policy types as well as those who specifically want irradiated foods—for example, those who are stocking up on potatoes for the fall (the previous winner) or people who are shopping on Monday for a special

The Radura

Symbol Mean?

dinner next Sunday.

The Radura, already in use in Europe, may become the acceptable option for American food processors if the required to consumer demands for labeling yes are afraid that the word "irradiation" may scare people into avoiding such foods. The Radura may make the choice to avoid irradiated food a little easier for the very well informed, yet would have negligible effect on the average consumer. (What you don't know can't hurt you, right?)

Other proposed labels which avoid the word "radiation" and its alleged misleading impression include: pasteurized, sanitized, processed by Pico waves or electrons, and gamma treated. Such euphemistic labeling could satisfy the food industry which won't lose any sales. Carefully planned marketing would be a key element in selling people irradiated food. According to Ide Young, "The important thing in marketing of course, is to explain and sell all the benefits, then add the symbol to the label so we can recognize the improved product." Without labeling, she maintains, "How on Mrs. Penny knows which are the clean, safe spices if they aren't marked, and French doesn't want anything but irradiated spices in the house."

Enough evidence has been gathered to show the serious drawbacks involved in irradiating food:

• Nutritional Degradation: Published studies show that carotene and vitamins A, E, C, B6, and B12, as well as essential amino acids that make up protein such as cystine, methionine, tryptophan, and histidine are affected by irradiation. One of the "homemaker's" reasons given to justify food irradiation is that it would prevent spoilage in food that could be

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The Politics Of Food Irradiation

by Terry Tamminen

Are you a label detective? Do you look to see what's in and what's been done to the food you buy? If your food were being irradiated, would you want to know about it? Or would you trust the Food and Drug Administration (FDA) which says that irradiated food is safe—in fact, that the agency sees no need to require it being labeled as irradiated?

PENDING LEGISLATION

For those of you who do care about what's been done to your food for your own good with or without your knowledge, your existing right to know may soon be gone. Legislation supporting the FDA's position on safety and labeling of irradiated food has been introduced in both houses of Congress (H.R. 556 in the House and its identical counterpart S. 288 in the Senate). In sum of purpose is to promote the development and commercialization of food irradiation, the process of treating food with ionizing radiation to retard spoilage, aging and insect infestation. To this end, it provides support for financing public acceptance and technological development of the process.

To help promote public acceptance, H.R. 696 would, if passed, amend existing FDA regulations, redefining food irradiation as a process rather than an additive. This would effectively lift any retail labeling requirements. Currently, food for retail consumers that has been irradiated must be marked, "treated with ionizing (or 'gamma' or 'electron') radiation." For a variety of reasons, irradiation of retail food products has not been widely used. More than there is a resistance of interest in the process, the FDA fears that the required label statement "could raise unfounded concerns that the food was radioactive or otherwise hazardous." In addition to the pending Congressional legislation, the FDA itself has proposed rule changes to promote food irradiation which will probably be acted upon by the end of the year.

WHO SUPPORTS FOOD IRRADIATION?

Food and agriculture industry leaders, manufacturers of irradiation equipment, and the U.S. Department of Energy (DOE) concur with the FDA's conclusions and all heartily support the proposed legislation.

The National Pork Producers Council President Wayne Wolter, testified before a House Subcommittee on Energy Research and Production that food irradiation holds great promise for the elimination of trichina from pork. He said, "Our mission is to enhance the producer's opportunity for profit. We see the total elimination of the threat of trichinosis in pork as one way for producers collectively to realize greater profits."

Wolter and others who support food irradiation technology cite public attitudes about the process as a key factor influencing its personal development. The proposed legislation calls for "education regarding food irradiation by using radiation in order to promote public understanding and acceptance."

Allan Chin, President of Radiation Sterilizers, Inc. (RSI), a California company which owns and operates several large scale irradiation facilities for medical sterilization services, testified, "Consumer education and acceptance will certainly greatly influence the rate of growth of this application [of irradiation]."

RSI supports the proposed legislation for two reasons. First, the development of food irradiation technology creates a whole new market for the irradiator equipment industry, both at home and abroad. Second, the legislation provides for ensuring "adequate supplies of sources material by providing for the . . . leasing of nuclear byproduct material" for commercial food irradiation and the construction of existing export of nuclear waste byproducts.

The fuel for irradiators is derived from the nuclear wastes from weapons and energy production. These elements are Cobalt 60 and Cesium 137. Currently, almost all irradiators utilize Cobalt. Atomic Energy of Canada presently controls approximately 95% of the world's Cobalt. Most of the nuclear reactors in the United States, however, produce Cesium 137 as the principal waste byproduct rather than Cobalt. Domestic development of Cesium as irradiator fuel would ease RSI's and similar companies' dependence on Canada for Cobalt.

RSI's Allan Chin related to Congress that his company is "in desperate need of Cobalt or other sources of gamma rays."

> *. . . the FDA fears that the required label statement "could raise unfounded concerns that the food was radioactive or otherwise hazardous."*

Other sources include Cesium, of which there is currently only a two year supply in usable (i.e., encapsulated) form. The proposed legislation implies that licensing requirements for the leasing by the Government of Cesium to industry would be loosened to promote food irradiation technology development. Chin testified that "This material is not available to industry because of NRC restrictions. This material is currently wasting away in storage pools."

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BABIES REVOLT!!

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Foods Currently Being Irradiated

The following foods are currently included in the FDA additives regulations. These foods can be irradiated now, and under current FDA rules are to carry labels stating, "Treated with gamma radiation."

As of August 1985:

Pork
Dried Enzyme Preparations
Wheat, Wheat Flour
White potatoes

Herbs and spices:
Allspice, Anise, Basil, Bay leaves, Caraway seed, Cardamom, Celery seed, Chamomile, Chervil, Chives, Cinnamon, Cloves, Coriander, Cumin seed, Dill seed, Dill weed, Fennel seed, Fenugreek, Garlic powder, Ginger, Grains of paradise, Horseradish, Mace, Marjoram, Mustard seed, Mustard flour, Nutmeg, Onion powder, Orange peels, Oregano, Paprika, Parsley, Pepper (Black & White), Red Pepper, Peppermint, Poppy seed, Rosemary, Saffron, Sage, Savory, Sesame seed, Spearmint, Star aniseed, Tarragon, Thyme, Turmeric

All herbs and spices absorbed dose not to exceed 1,000,000 Rads.

Master irradiated foods which are used as ingredients in other food products do not have to be labeled at the retail level. For example, a TV dinner which contains irradiated spices does not have to indicate this on the label.

Are Food Irradiation Plants Safe?

by Colleen DeLaney

As if concerns about eating irradiated food are not serious enough, there are equally serious hazards involved in the use, handling, and transportation of radioactive materials that will be needed to operate food irradiation plants.

Food processing industry analysts predict that by the mid 1990's there will be over 1,000 food irradiation plants operating in the U.S., compared to 90 nuclear power plants. When one looks at the safety problems already plaguing the nuclear power industry, this figure becomes all the more alarming.

Disposing of the Cobalt 60 or Cesium 137 rods when their half-life decays and transporting and installing new ones means many opportunities for radiation leaks and disasters. John Gofman,[1] in *Radiation and Human Health*, estimates that if current industry were able to safely contain 99.9% of the Cesium 137 it uses, the .1% that escapes would be responsible for 290,000 cancer deaths per year. Even if 99.9% of the Cesium could be contained, there would still be 29,000 cancer deaths per year. One serious accident could release up to 10% of this material. And, given the fact that food plants will have to replace part of their radioactive source on a yearly basis, the chances for an accident are unacceptably high.

Although irradiating food does not make it radioactive, one tiny leak from the water surrounding the radioactive source (just the kind of water leak that has plagued nuclear power plants), could contaminate thousands of pounds of food which then would be radioactive. And radiation, like toxic chemicals, tends to concentrate as it works its way up the food chain. If a leak contaminated wheat fed to cattle or pigs, the amount would build up in their tissues—and then be fed to consumers. Or, the leaked water could find its way out into the surrounding environment.

Water has already leaked from Cobalt 60 processing plants, including one in Maryland, causing significant damage. And the food processing industry is not held to as high of standards as nuclear power plants, whose standards are arguably not high enough. While nuclear power plants are only allowed to emit 25 millirems of radiation per year, food processing plants are allowed 500 millirems per year.

Nor is the FDA proposing to require even minimal training for food irradiation equipment operators in radiation health physics, dosimetry, etc. Under current Federal regulations, a Spanish-speaking worker could be put in charge of food irradiation equipment bearing instructions in English only. When you consider that food is subjected to radiation on the order of 100,000 rads, and when you consider that a single dose of 300 rads will kill half the people exposed to it and sterilize the rest, this oversight seems incredible in an antediluvian sense.

So far the safety record for nuclear power plants has not been good. Thus new nuclear foods industry handles materials that are just as deadly—and under much less stringent guidelines. How long will it take for a major disaster to strike?

Food processing industry analysts predict that by the mid-1990's there will be over 1,000 food irradiation plants operating in the U.S. . . .

The Safety Of Food Irradiation

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shipped to hungry people in Third World countries who lack adequate refrigeration to store food. But for people in the Third World whose diets may rely on one or two staples, vitamin-depleted irradiated food could have serious health consequences. (This is reminiscent of Nestle's selling infant formula to Third World countries.)

• **Unique Radiolytic Products:** Radiation-induced chemical changes result in the formation of new chemical compounds called unique radiolytic products, or URPs. Part of what causes the color and flavor of some foods to change is these URPs. It is not yet known how many URPs are released in irradiated food, but the U.S. Army has already identified 42, including formaldehyde and peroxide. While it appears that most URPs are harmlessly digested, there is no way of knowing at this time to what extent these might be toxic, or what their long-term effect might be.

The FDA is leery of URPs, warning the Army in 1968 that feeding soldiers irradiated ham could have "a highly significant effect on reproductive processes" and that there was a "possibility of increased risk of cancers and tumors." And, in 1980, the FDA warned that foods irradiated at greater than 100,000 rads "may contain enough [radiolytic products] to warrant toxicological evaluation." Doses that high, and higher, are necessary to preserve many foods.

• **Toxins Released:** It is still not known what the maximum doses are that foods can handle without creating toxic effects. Tests on lab animals have had mixed results, and some of the most important studies were conducted by the notorious Industrial Bionic Laboratories, found guilty in 1983 of falsifying test data.

However, in 1984 the EPA released a report where it was found that irradiation of grains and vegetables stimulated the production of aflatoxins, a potent cancer causing chemical that is some 1,000 times more deadly than the EDB's banned last year.

• **Bacterial Resistance:** Bacteria and viruses can develop resistance to radiation, just as insects have developed resistance to pesticides. After all, microbes have already learned to live with natural background radiation. Some microorganisms may develop an immunity to radiation—an effect that has already been seen in laboratories—or worse, they can mutate under heavy doses, making them even harder to kill.

Since microorganisms can develop resistance, and some develop more resistance than others, removing one organism can allow others to grow, unimpeded. Irradiating chickens to kill salmonella may not harm the hardier botulism bacteria, which would then grow uncontrolled and be completely unnoticeable.

• **Radiation-Induced Diseases:** Research done in southern India, published in the 1975 American Journal of Clinical Nutrition, reported that irradiated food may be linked to leukemia, a blood cancer. In this study, all ten children fed irradiated food developed blood abnormalities associated with leukemia. The control group, fed non-irradiated food, showed no such abnormalities.

And a 1984 report released by the Department of Agriculture warned that two of the Department's studies "had some possible adverse findings which will require careful consideration before the process can be declared safe." In these study, mice that had eaten irradiated chicken showed an increased in testicular tumors, cancer, and kidney disease. Another study found radiation related increase in deaths among the offspring of flies who were fed the chicken.

In another study, children and animals fed newly irradiated wheat showed cells containing an abnormal increase in chromosomes. An in another study, rats fed irradiated oocytes were found to have ovaries or testes which differed significantly in weight from those of control animals.

Although proponents of food irradiation claim that this technology is completely safe and fully developed, there has not yet been one study proving the safety of food irradiation, and many studies casting doubts on the entire process. It remains to be seen whether Americans will accept food that will be nutritionally depleted, potentially toxic, and undoubtedly more expensive.

Colleen DeLaney is an instructor at Cabrillo College's School of Radiologic Technology and a writer on health issues.

The Politics Of Food Irradiation

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The U.S. Department of Energy is interested in technology that would reduce the waste of nuclear waste. The U.S. Government could become competitive with Canada in supplying the world with irradiated food at a lower price. A healthy profit stands to be made from the leasing of Cesium to the food irradiation and medical sterilization industry. Furthermore, the political and environmental problems of moving nuclear waste would allegedly be reduced. Therefore, DOE supports the proposed legislation, including provisions for eliminating labeling of irradiated food. Dr. F. Charles Gilbert of the Department's Nuclear Materials Defense Program testified, "The fact that food irradiation has been designated an additive rather than a process has been an impediment to food irradiation technology. This in turn forms the basis of an adverse public attitude. For years we have been exposing the public to ethylene dibromide (EDB), a deadly chemical, and now we are replacing it with something 'nuclear'."

IS IT SAFE?

In spite of the insistence by those most interested in the development of food irradiation technology that the process is safe, consensus does not exist in the scientific community on that point. John Graham, professor emeritus of biophysics and medical physics at UC Berkeley, asserts, "When you irradiate food, you provoke a number of chemical changes in the food. These may be absolutely no side effects or there may be serious long term effects in the form of cancer and effects on genes. It would take an enormous study of hundreds of thousands of people over 20 or 30 years [to determine long term effects]."

Government research designed to demonstrate the safety of irradiated foods has been conducted for almost thirty years. Those studies have been inconclusive until 1979. That year, a new committee of scientists from the Health, Education and Welfare's Division of Toxicology was formed to reassess a "all export issues applicable to food irradiation." This mill worker was filled in just one year. The committee basically concluded that sixteen thirty years of research could not prove food irradiation to be unsafe, it must therefore be safe at prescribed levels. The FDA based their conclusions that the process is safe and does not constitute labeling requirements on the committee's findings.

CONGRESSIONAL SUPPORT

Sponsors of the food irradiation legislation in Congress accept the FDA's recommendations. It is interesting to note that many of these Congressional sponsors represent districts or states which would benefit economically from the commercial development of food irradiation technology. Representative Sid Morrison (R.-Wa.), the author of H.R. 606, represents the district where Hanford Nuclear Reservation is located. (The current sole source of manufactured Cesium is stored at Hanford.) Hanford's economy is virtually dependent upon Government research and development contracts for nuclear technology. Government plans to encapsulate more Cesium for commercial leasing would prove quite lucrative to Morrison's district. Furthermore, a significant number of California representatives from areas where agriculture and food processing industries predominate have also signed on as sponsors. (This list includes Congressmen Leon Panetta and Ed Zschau, Santa Cruz County's representatives.)

LABELING IS THE ISSUE

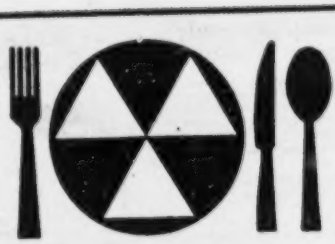
There are many who feel less than confident about the FDA's conclusions about safety of irradiated food. There is ongoing and increasing concern over the process' safety and the potential nutritional loss in irradiated food. Yet the largest concern seems to be about labeling. Opponents fear labeling will create undue fear and unnecessary harm to food producers' profits hold little water with consumers who insist on exercising their right to choose unirradiated foods.

One organization, the Coalition to Stop Food Irradiation (CSFI), is working to educate the public about the health, safety and right to know issues involved in the proposed FDA regulation changes. CSFI is also trying to get labeling legislation passed in local communities which would require clear labels on all irradiated foods. (Incidentally, the proposed U.S. legislation preempts any local or state labeling requirements.) The organization is urging people to contact their representatives and the FDA to express their concerns about safety and labeling of irradiated foods. Label distortions don't leave much time to keep inspectors close about what's been done to their food from disappearing.

For more information about efforts to require labeling on irradiated food, contact CSFI, Box 5183, Santa Cruz, Ca. 95063.

Terry Tamminen is the Executive Director of the Santa Cruz County Nuclear Weapons Freeze.

> *"For years we have been exposing the public to [EDB], a deadly chemical, and now we are replacing it with something 'nuclear'."*



A History Of Food Irradiation Regulations

- February 1963: FDA approved gamma radiation for the radiation preservation of canned bacon.
- August 1963: FDA approved gamma radiation for control of insect infestation of wheat and wheat products.
- August 1963: FDA approved electron beam radiation for the radiation preservation of canned bacon.
- October 1964: FDA approved gamma radiation for sprout inhibition of white potatoes.
- December 1964: FDA approved X-radiation for the radiation preservation of canned bacon.
- July 1966: FDA approved electron beam radiation for the control of insect infestation of wheat and wheat products.
- July 1966: FDA approved labeling requirements for food treated by radiation.
- October 1968: FDA rescinds the bacon regulations.
- September 10, 1979: Director, Bureau of Foods establishes the Irradiated Food Committee to provide a total reassessment of all relevant issues applicable to irradiated foods.
- March 27, 1981: Advance Notice of Proposed Procedures for the Regulation of Irradiated Foods for Human Consumption (ANPR) published in the Federal Register.
- Autumn, 1981: FDA offered the opportunity for use of irradiation for insect disinfestation during the California Medfly situation based on certain conditions. However, no firm furnished evidence of meeting those conditions.
- July 5, 1983: FDA approved gamma radiation for microbial decontamination of a specific list of spices and vegetable seasonings.
- February 14, 1984: Proposed rule published in the Federal Register. FDA proposes a regulation for sprout inhibition and shelf-life extension of fresh fruits and vegetables, for insect disinfestation of food, and for sterilization of spices.
- June 19, 1984: FDA amended the food additives regulations to provide for the safe use of a source of gamma radiation to control insect infestation in garlic powder, onion powder, and dried spices.
- September 26, 1984: Filing of Food Additives Petition by Radiation Technology Inc. to amend the food additives regulations to provide for the gamma radiation of certain dried herbs, spices and vegetable seasonings to control insect and microbial infestation.
- October 19, 1984: Radiation Technology filed a petition to amend the food additives regulations to provide for the use of gamma radiation to control insect and microbial contamination of Dried Enzyme Preparations.
- January 24, 1985: H.R. 606 introduced in the House of Representatives by Sid Morrison (R-Wa.) 99th Congress, 1st session
- April 18, 1985: FDA amended regulations providing the gamma radiation of expanded specific list of dried spices, herbs and vegetables seasonings.
- June 10, 1985: FDA amended regulations providing for the gamma radiation treatment of Dried Enzyme Preparations.
- July 22, 1985: FDA amended the food additives regulations to permit gamma radiation treatment of pork to control Trichinella spiralis, in response to a Radiation Technology petition.

Pending Food Irradiation Legislation

The specific purpose of the Food Irradiation legislation which has been introduced in both the House of Representatives (H.R. 696) and the Senate (S. 288) is "To provide Federal coordination for the continued development and commercialization of food irradiation . . ." The legislation provides for six basic steps to facilitate the commercialization of this controversial method of preserving food. These are:

1. **To change the definition of food irradiation from an additive to a process.** Under Food and Drug Administration rules, food irradiation is considered a food additive and therefore subject to labeling requirements for additives. This definitional change lifts legal labeling requirements.

2. **To expand research and development of food irradiation.** This implies research and development funds would be made available to institutions such as Battelle Pacific Northwest which conduct research on nuclear waste minimization.

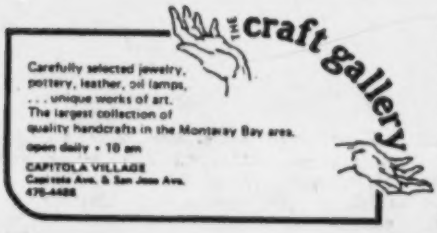
3. **To provide for education regarding food irradiation** "in order to promote public understanding and acceptance." This provision is included because proponents of food irradiation fear that public concerns and "misperceptions" about the effects of irradiating food would hinder its commercialization. Public education goes hand in hand with the lifting of labeling requirements—if people are convinced that the process is safe, the argument goes, there will be no need to label irradiated food.

4. **To provide for national uniformity in the regulation of irradiated food.** Any attempts by state or local governments to require labeling or other restrictions on food irradiation are effectively voided by this provision.

5. **To ensure adequate supplies of source material for use by commercial** food irradiators and exporters of irradiator source material. Source material is nuclear wastes from weapons and energy production. This means Nuclear Regulatory Commission licensing requirements for leasing nuclear byproducts would be relaxed, making it easier for the food irradiator industry to obtain the materials as well as facilitating an acquisition by exporters. Currently, Canada holds a monopoly on the world market by providing 95% of the world's supply of Cobalt 60, the nuclear by product now used in irradiators. This provision opens the market for Cesium 137, the nuclear waste produced in U.S. nuclear plants. U.S. distributors of Cesium would be able to compete with Canadian Cobalt dealers.

6. **To provide for the creation of a Joint Operating Commission for Food Irradiation** within the Department of Agriculture to serve as an intermediary with private enterprise, Federal and State government agencies, international organizations, and the public. This sets up a commission much like the old Atomic Energy Commission which was the government agency to promote commercial use of nuclear power after World War II. The Joint Operating Commission would serve the dual purpose of promoting and making recommendations on regulating food irradiation. This commission would basically facilitate the implementation of this legislation.

Representatives Leon Panetta and Ed Zschau have both sponsored the House Resolution. The legislation, on the surface, seems to deal with both the problem of what to do with nuclear wastes and minimizing spoilage and waste of the nation's food supply. Yet it also raises issues such as public health and safety since there is not widespread agreement about the long term effects of eating irradiated food. And finally, the definitional changes of food irradiation lifting the existing labeling requirements raises the basic issue of consumers' right to know what has been done to their food.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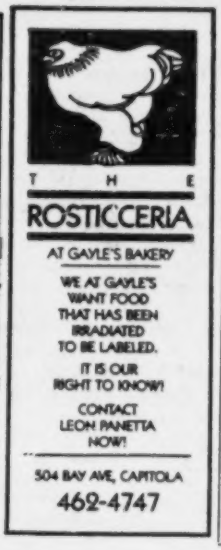
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Sources For More Information

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COLLEGE OF AGRICULTURAL AND ENVIRONMENTAL SCIENCES
AGRICULTURAL EXPERIMENT STATION
DEPARTMENT OF POMOLOGY

DAVIS, CALIFORNIA 95616

March 5, 1985

Mr. Paul T. Libassi, Editor
The Sciences
The New York Academy of Sciences
Two East Sixty-Third Street
New York, NY 10021

Dear Mr. Libassi:

Bombarding Bananas - Zapping Zucchini was written, I believe, with the intention of providing readers with timely and balanced information regarding the possible uses of gamma radiation to extend the shelf life of food. Unfortunately, examples relating to the postharvest life of fruits and vegetables were inaccurate, misleading or totally wrong.

I can only believe that the authors were writing in a field (postharvest diseases of fruits and vegetables) in which they have little knowledge. For example, the authors comment upon the array of chemicals that might be applied after harvest to oranges. They later state that "if deemed safe by the FDA and then widely used by the food industry, irradiation could replace the fungicides and insecticides now sprayed on fruits and vegetables." It would be nice to be able to reduce our dependence upon fungicides. However, there is utterly no possibility that gamma radiation, as we now use it, could possibly replace fungicides. Instead, there is considerable evidence to indicate that certain diseases of harvested citrus fruits would be more active after irradiation. Radiation-induced cellular injury and the onset of senescence causes a reduction in the normal level of the commodity's disease resistance.

The late Dr. Edward Maxie and I concentrated on studies of the use of gamma radiation to control postharvest diseases of fruits and vegetables for 10 years (1963-1973) with support from the Atomic Energy Commission. We found that in citrus fruits, a dose of 200 krads was required to delay disease development by the pathogens Penicillium digitatum, P. italicum, or Geotrichum candidum. Diseases caused by Alternaria alternaria or Diplodia natalensis were often worse in irradiated than in non-irradiated citrus fruits. Partly that was so because the fruits calyx was weakened by irradiation to permit entrance into the fruit at the stem end.

Citrus fruits could not tolerate the 200 krad dose required for minimal suppression of disease fungi. After 200 krads and subsequent holding periods equivalent to the time required for transportation and marketing, the oranges (Navel and Valencia) exhibited the following: the albedo was abnormally soft, the fruit surface was often pitted, and the taste and aroma were noticeably different than unirradiated controls. Lemons irradiated before storage to reduce disease during storage suffered much more rot than the non-irradiated controls. Injury was

noted after storage in fruits irradiated with as little as 25 krads and severe injury was found in fruits that had been irradiated at 50 krads or higher. Further, citrus fruits are chilling sensitive and are damaged at refrigerated temperatures well above freezing. Irradiated fruit clearly exhibited increased susceptibility to the damaging effects of chilling injury.

A search of the literature of the past 25 years would have, at a minimum, alerted the authors that plant scientists had discovered serious problems with irradiation. Hatton, et al., recently reported that as little as 60 krads caused excessive injury in the form of scald and rind breakdown of grapefruit. Injury classed as moderate occurred at 15 and 30 krads but the authors judged those fruits to be acceptable. (T.T. Hatton, R.H. Cubbedge, L.A. Risse, P.W. Hale, D.H. Spalding, D. von Wideguth, and V. Chew. 1984. Phytotoxic responses of Florida grapefruit to low-dose irradiation. J. Amer. Soc. Hort. Sci. 109(5):607-610).

The authors also wrote "irradiation could reduce spoilage which now ruins an estimated 25 to 30% of the world's food supply. It would extend shelf life of products for weeks, increasing the length of time food could be stored or transported and still taste fresh, while decreasing the need for many of the chemical preservatives now used for this purpose." It is doubtful that any fresh (living) commodity's shelf life would be increased more than a few days by using irradiation to control rot organisms.

Quoting the authors further, "Irradiation is desirable not only because its effects are so lasting but because it 'cold-processes' food. This means that the gamma ray bombardment heats the food only slightly, minimizing adverse changes in color, odor, flavor, texture, and nutritional value. Thus, the technique is superior to both canning and freezing, which often leave food mushy, rubbery, or mealy." As a matter of fact, changes in color, odor, flavor, and texture are generally what one does complain about after fruits or vegetables are irradiated at doses that even minimally suppress postharvest pathogens. As for nutrition, the authors are evidently unaware that irradiation causes destruction of vitamin C.

Further on the authors said "the industry began to envision strawberries on fruit stands remaining bright red and firm for weeks." As a matter of fact, our experience showed that shelf life extention, from suppressing Botrytis cinerea, varied from essentially nothing to as high as 8 days. On average, however, there was generally an extension of 3 or 4 days. Some strawberry cultivars would not tolerate the 200 krads at all.

Sincerely,

Noel F. Sommer
Lecturer and Postharvest Pathologist
University of California, Davis

NFS:km

California Fruit Grower. May, 1984 . Blue Anchor Co-op
Vol. 61 No. 5. pp. 25-28. Sacramento, California

Irradiation As A Possible Quarantine Treatment For Fresh Fruits And Vegetables

Gamma irradiation has been highly publicized as an "available" alternative to EDB fumigation. In this report, the authors state these stories are overly optimistic for many reasons.

Noel F. Sommer and F. Gordon Mitchell
Department of Pomology, University of California, Davis, CA 95616

The multubillion dollar California fruit and vegetable industry is under threat because of actual or potential quarantines which may be imposed within hours or days if any one of a number of insect pests are introduced into California. The Mediterranean fruit fly (*Ceratitis capitata*) infestation of 1980-82 was eradicated but new infestations of the medfly or other tropical fruit flies are possible at any time.

Fumigation chambers have been widely constructed for treatment to satisfy quarantine requirements. However the scheduled withdrawal of registration of ethylene dibromide can leave the industry without a satisfactory quarantine treatment in the event of a new infestation.

Fumigation Chambers

Fumigation chambers have been widely constructed for treatment to satisfy quarantine requirements. However, the scheduled withdrawal of registration of ethylene dibromide because of possible health hazards could leave the industry without a satisfactory quarantine treatment for some important commodities in the event of a new infestation. An alternative to EDB is methyl bromide (MB). Unfortunately, MB is a fumigant which is phytotoxic to many fruits and vegetables. Further, MB has also been criticized because of possible health hazards. A cold exposure (10 days at 32°F to 16 days at 36°F or below) is an approved quarantine treatment for control of some of the fruit flies. Cold treatments can be used on some commodities (i.e. apple, grape, kiwifruit, orange, persimmon, pomegranates) but are not suited for short-lived fruits such as berries or stone fruits or for chilling sensitive fruits (e.g. avocado, grapefruit, lemon, pepper, tomato). Heat treatments and alternative fumigants under investigation may prove suitable for some fruits.

Gamma radiation has been highly publicized as an "available" alternative to EDB fumigation. Current interest is fueled by a recent FDA announcement of intent to allow treatments not to exceed 100 Krad (1kGy) in foods. Such treatment has been described by enthusiasts as a safe, effective, economical treatment now ready for use. While pest studies do suggest a potential for insect control, a number of considerations dictate extreme caution. We are most concerned about the lack of definitive information in a number of areas including the economics of the treatment and about the enormous logistic problems likely to occur with any widespread use of gamma irradiation.

Background

During a period of nearly 10 years, the U.S. Atomic Energy Commission (AEC) financed intensive and extensive studies at the University of California at Davis on the use of radiation to extend the shelf life of fruits and vegetables. The authors, along with the late Prof. E. C. Maxie, were principal or Co-Principal Investigators in those studies. Companion studies on the effects of radiation on the biochemistry of fruits and vegetables were done by Dr. R. J. Romani.

Florida and Hawaii Studies

Studies were also done in Florida and Hawaii on fruits and vegetables produced at those localities. To a large extent, knowledge about the

effects of radiation on living (fresh) fruits and vegetables were obtained in these AEC supported studies. Generally, it was concluded that the shelf life extension due to irradiation at 100-300 Krads was very short, often no more than 2-5 days at optimum refrigerated temperatures. All too frequently the shelf life was significantly shortened, not extended, by the radiation treatment.

While pest studies do suggest a potential use of gamma radiation for insect control, a number of considerations dictate extreme caution.

Unfortunately, insect eradication was not an objective of our studies. Consequently, much less is known about the effect of doses <100 Krad than between 100 and 300 Krad. Nevertheless, doses <100 Krad were used in such studies as sprout inhibition in onions and garlic in storage and the retardation of asparagus spear elongation and curvature in transit. These and similar studies gave some insight on levels of phytotoxicity which may occur at doses >100 Krad.

Radiation Biology

Cellular effects: Gamma rays which are produced by cobalt 60 and cesium-137 cause ionizations when they collide with matter (i.e. they are capable of knocking out electrons from atoms or molecules). The result of the collision is often to produce damage to parts of the living cell. During ionization, highly reactive free radicals are produced which react in various ways to also produce damaging events in cells. With a water content of 85-90% in most fresh commodities, the most common free radicals are those of water. Space within tissues comprise up to about 20% of the volume of many horticultural commodities, depending upon the species, so free radicals from oxygen are also likely to be important.

Much research relating to cell death has concerned damage to genetic material. If ionizing events occur in the DNA, breaks in the molecular chain may be the consequence. Because there is little redundancy, damage to the DNA may prevent cell division and, ultimately cause death.

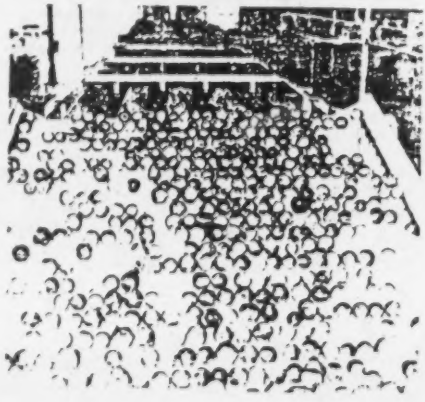
Cell Studies

Studies of events leading to death of cells most commonly involved single celled microorganisms. Cell death was an unambiguous end-point. Further, techniques of cytology and genetics were ideally suited for such studies. In multicellular targets, such as tissues of fruits or vegetables, the results were seldom so clear-cut as life or death. Many cells comprising tissues of mature fruits have discontinued division so that the consequences of DNA destruction may be less severe. That injury is occurring, however, is evident from several events that can be precisely measured in respirometers. In whole fruits and vegetables, an unmistakable and definitive increase in ethylene evolution is a common response to physical injury and can readily be measured by gas chromatography. The rate of respiration, as measured by carbon dioxide evolution or oxygen consumption, is routinely determined in postharvest laboratories. An abrupt increase in the respiration rate follows irradiation and that increase is related to dose although the physiological condition of the fruit or vegetable influences its ability to respond to physical injury.

Another consequence of irradiation which happens very quickly is tissue softening resulting from the effects of irradiation of cell wall components.

Some expressions of radiation injury can be observed only days or weeks after the irradiation. Effects of radiation-induced alterations of semi-permeable membranes can sometimes be seen, as well.

Some expressions of radiation injury can be observed only days or weeks after the irradiation. Effects of radiation-induced alterations of semi-permeable membranes can sometimes be seen. In sweet cherries, for example, membrane impairment resulted in a sticky exudate on fruit surfaces within a few days. Similar cellular exudation from the interior of cells to intercellular spaces within fruits is believed to be a common phenomenon although it may not be noticeable at the fruit surface.



Cold treatments can be used on some commodities such as grapes, oranges and kiwi fruit—but are not suited for short lived fruits such as stone fruits.

Distinctive and often unpleasant flavors or odors may be noted very soon after irradiation and may intensify with time after irradiation. Ripening may be delayed in some fruit species but hastened in others, possibly in response to the production of wound ethylene. In time, such symptoms as skin or rind pitting, flesh or skin browning, loss of chlorophyll or other aspects of tissue senescence may be observed.

Irradiated fruits or vegetables may be noticeably more susceptible to infection and colonization by postharvest pathogens. Increased susceptibility to mechanical injury from handling or transportation may be observed in irradiated fruits. Similarly, a greater tendency for fruits to shrivel, as a consequence of moisture loss from tissues, is frequently seen following irradiation.

Radiation Effects

All radiation effects must have occurred as a consequence of cellular or tissue injuries or disturbances. That is true whether the effect is immediate or the result of altered physiological activity over an extended period. Further, when a commodity containing an undesired insect or fungus is irradiated, the target pest or pathogen and the host are both injured. To be successful, the irradiation must achieve a beneficial effect without inflicting unacceptable damage or changes in the host commodity. If prevention of sprouting of potatoes or onions is the desired effect, the irradiation must seriously damage buds or growing points without unacceptable injury to other tissues.

Irradiation in the absence of oxygen (anoxia) reduced the amount of injury to fruits, at a given dose, by about one-third below that experienced when irradiation was in air. That beneficial effect was likely the result of the absence of free radicals of oxygen when irradiation was performed in anoxia. The benefits of irradiation in anoxia appeared to be small, however, because the radiation effects would be reduced in both host tissues and the tissues of the target insect pest or pathogen.

Differences in temperature during radiation are not likely to materially influence the effects of irradiation of fruits and vegetables. From the standpoint of good temperature management, however, there would be considerable benefit in not breaking refrigeration during irradiation. Further, because irradiated fruits and vegetables may be more susceptible to rot organisms, good temperature management would become even more important in subsequent fruit handling.

Irradiation Dose For Quarantine Treatments

At the time of preparation of this paper, considerable uncertainty existed regarding the irradiation dose that will be required to satisfy quarantine requirements. For fumigation, a killing level has been required in which <32 individuals per million would survive. Some say that, with radiation, insect death should not be the criterion. Instead, the argument goes, the level should be that dose at which <32 individuals are still capable of reproduction. The required dose is very important from the standpoint of cost. Further, the higher the dose, the more likely problems of phytotoxicity will be encountered.

The fear that radiation from gamma ray irradiation from isotopes might be induced in fruits and vegetables appears to be entirely groundless.

In using gamma rays from isotopes to irradiate fruits and vegetables, it is sometimes believed that radiation might be induced in the commodity. That fear appears to be entirely groundless. Undesirable changes in component molecules do occur, however, as a consequence of ionizing events. Especially noted has been the radiation-induced destruction of certain vitamins in fruit and vegetables to thereby reduce the nutritive value. The extent of vitamin destruction is dose related. Vitamin loss will vary from commodity to commodity and will be influenced by storage and handling procedures.

Radiation-induced chemical changes also result in the formation of new chemical compounds during irradiation. The extent to which these products might be toxic is not well known. Presumably the extremely low concentration of these unique radiolytic products limit their seriousness if they are toxic.

Irradiated rations have not resulted, to the best of our knowledge, in serious adverse responses of test animals. It should be understood, however, that radiation cannot be tested in the same manner as chemicals. In the latter case, test chemicals can be added to animal diets in massive amounts. Comparable massive irradiation would seriously alter the nutritive value of the diet. Further, it is difficult to feed test animals, such as dogs or rodents, a diet consisting largely of fresh fruits or vegetables.

The concentration of relatively large amounts of an isotope in irradiators may pose concern. Isotopes are safe when shielding is used through which commodities must be passed to be irradiated. The rays are absorbed by walls of lead bricks, concrete, or by placing the isotopes in chambers under water or deep underground. Events leading to loss of shielding must be rigorously defended against because of serious consequences to workers in the facility and possibly to nearby populations. Earthquakes, vandalism or terrorist action are events that could lead to serious consequences.

It is clear that considerable expertise of a type not usually associated with the fruit and vegetables industries would be needed if fruits and vegetables were to be widely irradiated.

Costs

Source factors. Sources for quarantine purposes are likely to utilize the isotopes cobalt-60, with a half life of 5.27 years, or cesium-137 with a half life of 30 years. The isotopes are equally effective in irradiating fruits and vegetables. Cost of the isotopes, in relation to the half life, is a major factor in determining the choice between the two isotopes.

A considerable capital investment is involved in the cost of isotopes, providing shielding, in mechanisms for exposing the commodity to the radiation source and instrumentation required for safe operation. Additionally, for fresh fruits and vegetables, refrigerated facilities must be provided for the accumulation of product before and after irradiation and for loading and unloading trucks. A fleet

of refrigerated trucks must also be available for transfer to and from the irradiation facility.

Fruits and vegetables are most commonly handled on pallets and these would be an advantage to irradiate pallet loads. A radiation source of sufficient size to provide reasonably narrow differences between minimum and maximum doses would be required. On the other hand, if pallet loads are to be depalletized in order to irradiate individual cartons separately, it will be essential that satisfactory equipment for palletizing and depalletizing the various types of cartons now in use would be required. Due to the magnitude of the California horticultural industry, extremely large volumes of produce would require such handling. It is not certain that existing palletizing-depalletizing machines are suitable.

Minimum-maximum doses: The upper and lower limits of doses are determined by the configuration of the radiation field and the size, shape and density of the product and its homogeneity. For quarantine purposes, minimum dose based on the insecticidal properties of the radiation plus a suitable margin of error must be established. Thus the legal minimum dose would be only slightly higher than the technical minimum dose. For example, if it were determined that a dose no lower than 25 Krad was required, a dose of 30 Krad might be set. If the minimum-maximum doses were a factor of 2, some commodities would be irradiated at a dose of 60 Krad. The max: min doses are extremely important from the standpoint of irradiator costs and the extent of phytotoxicity experienced by fruits and vegetables.

Factors in operation: Many of the costs of irradiation continue if the radiator is not in use. The isotopes continue to decay regardless of use, the facility must be maintained, safety must continually be assured. Ideally, a radiator would be utilized to capacity for 24 hours a day for 365 days a year. Unfortunately, horticultural commodities tend to be seasonal and highly variable in quantity during the season. The concentrated period of harvesting and handling most fruits and vegetables seldom exceeds 3 months at any location. It is not certain to what use radiators would be placed during the offseason. At present there are few commercial uses for radiators for purposes other than surgical and medical supplies and equipment, a limited amount of package sterilization, and the sterilization of spices. Irradiation of sewage sludge is another potential use.

Radiation sources would appear unable to easily expand in crisis situations. Let us consider the worst case in which a quarantine was established requiring disinfestation of all fruits and vegetables to be shipped outside the state. To meet that demand it has been estimated that 57 radiators of similar capacity to a Japanese potato irradiator, would be required in Fresno County alone. It seems to us extremely unlikely that either the capital investment or construction time would be available to permit rapid expansion of radiation facilities in a crisis.

Current Herbicide Label Status For Deciduous Fruit

Listed below is a table showing the status of the available herbicides on deciduous fruit and nut crops. Some uses may be for non-bearing trees only.

Material	Almonds	Apples	Cherries	Grapes	Kiwi	Peaches	Pears	Pistachios	Prunes	Walnuts
PREEMERGENCE HERBICIDES										
dichlobenil (Casoron)	R	R	R	R	—	R	R	—	R	R
dinoseb (Premerge 3)	R	R	R	R	—	R	R	—	R	R
diuron (Karmex)	—	R	—	R	—	R	R	—	—	R
EPTC (Eptam)	R	—	—	—	—	—	—	—	—	R
napropamide (Devrinol)	R	R	R	R	R	R	—	R	R	R
norflurazon (Solicam)	R*	R	R*	R*	—	R	R	—	R	R
oryzalin (Surflan)†	R	R	R	R	R	R	R	R	R	R
oxyfluorfen (Goal)†	R*	—	R*	R*	—	R*	R*	R*	R*	R*
simazine (Princep)	R*	R*	—	R*	—	R*	R*	—	—	R
terbacil (Sinbar)	—	R	—	—		R	—	—	—	—
Trifluralin (Treflan)	R	—	—	R	—	R	—	—	R	R
FOSTEMERGENCE HERBICIDES										
dalapon (Downpon M)	R-S	R	—	R	—	R	R	—	R	—
glyphosate (Roundup)	R	R	R	R	—	R	R	R	R	R
dinoseb (Dow General)	R	R	R	R	—	R	R	N-B	R	R
MSMA (Bueno 6)	N-B	N-B	N-B	—	—	N-B	N-B	—	N-B	N-B
paraquat (Paraquat CL)	R	R	R	R	R	R	R	N-B	R	R
2,4-D (water or OSA)	R-S	—	—	—	—	R-S	R-S	R-S	N-B	R-S
weed oil	(No registration required. Safe for all crops if NO trunk contact.)									

R = Registered
R-S = Registered State Label only (some uses may be for special local needs only)
N-B = Registered for use in non-bearing only
— = Not registered
R* = Registered with restrictions (not applied after February or not applied on coarse soils, etc.)

NOTE: The 4AS formulation (solution) of Surflan is incompatible with Goal 1.6E *unless* the Surflan 4AS is added *first*, agitated well, and then the Goal is added.

NCSFI

National Coalition to Stop Food Irradiation

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NATIONAL COALITION TO STOP FOOD IRRADIATION ADDITIONAL TESTIMONY FOR THE PUBLIC RECORD IN RE H.R. 696

ABSTRACT

At this time there are no techniques for inspecting irradiated foods, no certain dosimetry, no actual enforcement of the labeling law, no FDA list of irradiating facilities, no record of what is being irradiated, no record of how much is being irradiated annually, no determination of adverse health effects from consumption of URP's or of food depleted of various nutrients, amino and nucleic acids. Proponents attempted to dismiss the distinction between "additive" and "process", however, this change is the cornerstone of HR 696. Either the author(s) of HR 696 (and of S 288, HR 3504) went to alot of trouble for nothing, and the change should be deleted from the bill, or the difference in these classsifications is substantive and should be acknowledged.

December 13, 1985

House Agriculture Subcommittee
on Department Operations, Research
and Foreign Agriculture
Room 1301
Longworth House Office Building
Washington, D.C. 20515

Honorable Chairman Berkeley Bedell and Distinguished Members:

We are submitting to the Committee additional testimony to correct what we believe were misleading statements by proponents of food irradiation. Also enclosed, at Chairman Bedell's request, is information on the British experience with food irradiation and concerned citizen movement in that country.

First, we'd like to clarify Congressman Pat Robert's remark that "food irradiation is an important and safe alternative to pesticides..." made during the November 18, 1985 hearing before your committee. While we, too, wish to see the use of pesticides discontinued, we wish to point out that food irradiation will only be able to replace the chemical category of fungicides, and then only in quarantine circumstances. This narrow application is not sufficient grounds to establish an industry with such far-reaching and lethal consequences both to consumers and to our communities. We include here a letter Dr. Noel Sommer addressed to Mr. Paul T. Libassi, editor of the Sciences of the New York Academy of Sciences, on the feasibility of irradiation replacing fumigants. We have also attached Dr. Sommer's article,"Infeasibility of Ir-

radiating Fresh Fruits and Vegetables." Dr. Sommer worked under contract with the Atomic Energy Commission between 1963 - 1973 on the irradiation of fresh fruits and vegetables at the University of California at Davis, California.

Senator Tom Harkin suggested that if irradiated food is to be so labeled, than all chemicals in food should be labeled. His proposal, however, is raised to obscure the issue of the Consumer's Right to Know. Senator Harkin's suggestion makes the current law requiring labeling of irradiated food, and the consumer demand for its enforcement, seem infeasible and too complicated. The current law, 21 CFR 179.22, must be strictly enforced, regardless of the presence of residual chemicals, pesticides, steroids and hormones found in foods. Then let us draft legislation requiring that all potential toxins found in food or used in its processing and growing be identified on the label.

Currently the FDA administratively applies the labeling code only to foods which are sold as they are irradiated. In practice this results in unlabeled irradiated foods, as most foods irradiated wind up as ingredients in other food products. We believe this violates the Congressional intent and requires some expression of your committee to redirect FDA to label all irradiated food ingredients. We have been informed by FDA that a can of irradiated potatoes, for example, does not require labeling because it also contains unirradiated water and salt. Please see accompanying letter from Dr. Pauli confirming this FDA interpretation of the labeling requirements

One concern of ours is that the reality of irradiating food will continue to be confused with hyperbole from enthusiastic proponents of nuclear technology. On November 18, 1985, Congressman Sid Morrison waxed enthusiastically that "food irradiation is the most revolutionary post-harvest treatment since canning and freezing in the 19th Century." Almost simultaneously he acknowledged that the most useful application of irradiation is as a post-harvest fumigant. The number one problem which food irradiation actually addresses is that of killing varied species of fruit fly. This is hardly worthy of the description "revolutionary." We mention this flattering description of food irradiation because it sets a tone which allows for the dangerously misleading claim that irradiation of food destroys botulism in meats, poultry and fish.

Irradiation may kil Clostridium botulinum spores at mega-rad dosages, however the doses to which all references must be made are the doses which have been determined may not be harmful to consumers. At 100,000 rads the botulism causing spores are not only not killed or even sterilized, but, in fact, may be enhanced because the ecology is "cleansed" of most other microorganisms and of some organisms which indicate spoilage. Enthusiasm and salesmanship may not be appropriate even when selling cars, but never when selling legislation which affects public safety.

The Joint Expert Committee states in their 1981 Report: "Irradiation that does not exceed 220,000 rads (average dose) is expected to leave enough spoilage organisms to render the food unacceptable before cells derived from surviving C. botulinum spores can produce enough toxin to constitute a hazard. However ...other effective measures...will be necessary as well." [1, 2]

Our concern is obvious. Under these circumstances of competition between public health and the vested nuclear interests for the legislative ear, hyperbole becomes the byword of the proponents. Statements intended to sell rather than to be simple expressions of truth become all too commonplace.

Since Clostidium botulinum is not sterilized at doses 3 - 4 times the 100,000 rads proposed by the FDA but is one of the microorganisms cited by proponents as reason for allowing irradiation of food, there will be immediate pressure on the FDA to increase the ceiling to above 100,000 rads. In support, testimony is already being introduced by nuclear "scientists" telling how safe irradiated food is at higher doses and FDA openly encourages it. Witness the following dialogue before your committee on November 18, 1985:

Subcommittee question (Congressman Roberts or Chairman Bedell?)

"Do you gentlemen suggest that...once you made the initial approval that we can see a whole series of approvals of uses of irradiation?"

Dr. Young

"We would predict at this moment that there would be an increased use of radiation for food products...We would anticipate looking at a case by case level beyond that (100,000 rads)..."

Dr. Miller

"The answer to your question directly is 'yes' because basically the chemistry is the same, and we know a great deal about radiation chemistry that we learned over the past 100 years perhaps and our chemists then predict whether or not there would be anything special about a particular product...and then we would know we'd need to have these special studies done..."

Congressman Morrison

"As I understand that you're proceeding with the 100,000 rad limit ...that your level is only 1/10th of the level approved in other parts of the world?"

Dr. Young

"Yes...and thus it is below what is being used in some of the 21 countries that have used this process for some particular foods to date."

Congressman Morrison

"So, in essence, you are establishing that level below which you probably will not have to do a tremendous review, however you will consider petitions, as you have in the past, for treatments above that level, as we gradually understand better some of the desirable commercial implications of higher levels of treatment?"

Dr. Miller

"Exactly, we try to encourage the industry to come ahead with petitions (for higher dose application) on individual food items, providing appropriate data, indeed, in most cases have laid out what kinds of additional studies we would need in order to fill in what we think the holes might be for any particular product. And so, in the case of chicken, we have indicated certain studies we think need to be done..."

It is, indeed, already evident that FDA and Congressman Morrison are very interested in higher dose applications. Again, listen to the following conversation from the November 18, 1985 hearings:

Congressman Morrison

"As I recall from reading the World Health information they did not find undue risks at ten times the level of treatment you are proposing."

Dr. Young

"There is no question, at higher levels others have thought that there was not particular risk as well...And also it would be very difficult at 100,000 rads to detect any changes..."

Dr. Miller

"The problem was and is that the data base on which the Joint Expert Committee reached their conclusions was, in our opinion, had some questions concerning the studies that were used...We decided that we would like to proceed at the levels above 100,000 rad in an orderly fashion looking at products one by one, rather than trying to reach a generic conclusion. So for the moment, e.g., we are looking at some data concerning the use of levels above 100,000 rad on to prevent Salmonellasis in chicken...In conclusion, at 100,000 rad we are convinced that generically that is a safe dose."

We notice that Dr. Young does not confirm that food is safe above 100,000 rads even though Congressman Morrison pressed him on this point. Dr. Miller expresses the Agency's serious reservations about the data base upon which the Joint Expert Committee based its conclusions that irradiated food is safe and wholesome and upon which most other nations (if not all such nations) considering irradiation of food relied.

What are the FDA reservations and considerations in re the Joint Expert Committee's data base? What are the questions Dr. Miller and other FDA administrators and scientists have raised which remain unanswered by the Joint Expert Committee data base and conclusions? Dr. Takahashi Kosei of Japan in his 1983 review of the Joint Expert Committee work asserts that their conclusions were not supported by re-analysis of toxicological data from a perspective of radio-chemical examination of foodstuffs as complex systems, nor from experimental results.[3] Dr. Kosei's review of the literature was submitted November 18, 1985 as part of the testimony for the public record by the National Coalition to Stop Food Irradiation:

Further Problems and Conclusion

The above analysis revealed three important facts. The first was that the unconditional acceptance of irradiation of potatoes, onions, wheat and rice at a specified dose by the Joint Committee of FAO/IAEA/WHO was not supported by the re-analysis of toxicological data.

The second was that the theoretical approval of the safety of all kinds of food irradiated at a dose of up to one million rad was not supported either from the viewpoint of radio-chemical studies on food stuffs as a complex system, or from the experimental results.

The third was that the clearance for irradiation of food items granted in 22 countries as shown in the chart provided by the IAEA was specified by the answers to questionaires on the point whether it was for human consumption or not. Finally the number of countries that permitted irradiated food for human consumption was reduced to 14 (excluding 4 countries who did not answer the questionnaires)

The major countries where irradiated foods were actually supplied to the public were South Africa, the USSR and the Netherlands. Furthermore the major food stuffs irradiated and supplied in the market were potatoes and onions in four or five countries. Only one third of clearance granted (effectively applied for actual human consumption) was to be far reduced compared with that shown in the list provided by the IAEA. In 1972 the IAEA started a Regional Co-operative Agreement for Research, Development and Training Related to Nuclear Science and Technology (RCA) in the Asia-Pacific Area. The member countries of RCA are Australia, Bangladesh, India, Indonesia, Korea, Malaysia, Pakistan, the Philippines, Singapore, Srilanka, Thailand and Japan.

Japanese researcher T. Kawabata, member of the RCA Project on Food Irradiation informed in 1981 that IAEA had a plan to present irradiation facilities to the Philippines, Srilanka and others within 3-4 years. The data on the safety of fish, fish products and fruits must be re-examined for the sake of the peoples of these countries and especially for the people of Japan which imports a large amount of foods from these countries.

Finally the author would like to stress that this report casts grave doubts on the reliability of scientific activities of International Organizations such as FAO, IAEA and WHO.

We are frightened by the prospect of FDA following the lead of the Joint Expert Committee which is following the lead of the International Atomic Energy Agency whose mandate is the promotion and extension of nuclear technology into non-military areas. We are equally disturbed by the Joint Expert Committee's systemically minimizing the adverse effects of radiation on vitamins such as Vitamin C and thiamine, and its casual dismissal of radiolytic products where similar products may be found produced in non-radiation treatments of food. The Joint Expert Committee ignores the qualitative impact of increased quantities of radiolytic products which will be formed from irradiation of pesticides, insecticides, hormones, steroids, anti-bodies and other chemical residues found in food.[1]

We ask - are all the radiolytic compounds produced by other than irradiation treatments non-toxic? As the quantities of radiolytic products increase, does their toxicity increase?

It is common knowledge that it may take only a few parts per billion to cause cancer. In the rush to apply nuclear technology to our food, is this fact being considered too lightly or not at all?

The studies upon which the Joint Expert Committee relied examine volatile radiolytic compounds. What are the specific residual radiolytic compounds which are produced by irradiation? What will their effect be on humans, on the one in ten Americans who is allergic, on the young, the pregnant, the malnourished and the elderly? How much will the additional radiolytic products of irradiation add to the total toxic load Americans now carry in their lives?

The following exchange between the Committee and Drs. Young and Miller on November 18,1985 reveals the direction research must take:

Subcommittee Question

"At the sterilization level can you detect changes?"

Dr. Young

"AT the sterilization level we would be much more able to detect these changes over a period of time."

Subcommittee Question

Can you detect changes in the food that is irradiated at sterilization level?"

Dr. Young

"I would predict that we would be able to see some changes in some of the fine residues. This has not been analyzed carefully to my knowledge to give a detailed knowledge of each of the nutrients.

Dr. Miller, could you provide...?"

Dr. Miller

"You do find changes in these products. They are not uniform from product to product so that you can't say, well, if you find this one particular chemical, it means it's been irradiated. But the fact is that as the dose goes up the more products are produced in the product...The real question is, are those residues toxic?"

FDA must establish the health effects of long-term consumption of residual non-volatile radiolytic products, including the unique radiolytic products, and of consumption of gamma depleted and gamma destroyed nutrients such as beta carotene and Vitamins A, B1, B2, B3, B6, B12, C, K and E.

Beyond this research, the dosimetry must be established which will enable field inspectors to determine if a product has been irradiated, at what dose, if it has been re-irradiated, and to measure quantity of radiolytic products. How will FDA, USDA and HHS regulate this industry for the public's health if field inspectors have no means of determining the fact or extent of irradiation, as Dr. Young stated on November 18, 1985: "We've said again and again that an area of research that is absoslutely required is post-irradiation dosimetry. How can we, in fact, detect that the product has been irradiated?"

Is food irradiation regulated? What agencies will be responsible for its regulation?

At this point in time, FDA does not compile a list of companies irradiating food. Companies treating food with radiation need not register with FDA. FDA claims not even to have a list of facilities which have treated food with irradiation. FDA has no list of the foods and spices which receive the treatment nor the quantities treated per year. How does the FDA carry out inspections if it has no such information on who, what, where and how much? How does FDA know of "serious problems" if it does not have this critical information? Companies using irradiated foods are not required to report this fact to FDA. So how will FDA monitor the public's health? Is this another absestos cover-up? 4

FDA is required by law to enforce labeling of irradiated food, but has sidestepped this requirement by "interpret(ing) that regulation to apply only to a food that has been irradiated, not to a food that contains an irradiated ingredient." 4

At this time there are no techniques for inspecting irradiated foods, no certain dosimetry, no labeling in practice, no lists of irradiating facilities, no records of what's being irradiated, no record of how much food is being so treated, no tracking of where this irradiated food is going, no determination of the adverse health effects of long-term consumption of radiolytic products

or of depleted and destroyed nutrients, amino acids, and nucleic acids. There is, it seems, no control whatsoever.[4] HR 696 appears as the next legal step in deregulation of an ultra-hazardous industry.

Two final points. The cornerstone of HR 696 is the change in classification of food irradiation from the "food additive" to "process" category. If this would not change the FDA food safety requirements, **then why have all food irradiation proponents, including Congressman Morrison, pushed so hard for this change?** Hugh C. Cannon, Associate Commissioner for Legislative Affairs, FDA, states in his letter of October 31, 1985 to Congressman Leon Panetta that HR 696 would not substantively change Federal food irradiation labeling requirements or the sections setting forth the FDA labeling authority except as to the words "process" and "additive".[5] **Either the author of HR 696 went to alot of trouble for nothing, or the difference in these words is substantive. It cannot be both ways,** and it is abusive of the public trust in legislators to conceal the real purpose of such legislation.

The operative word here is "adulterative." It is a presumption of food additive legislation that an additive may adulterate a food, and food safety thus requires "rigorous scrutiny." Such a presumption of adulteration does accompany "process" as we spelled out in our oral testimony presented November 18,1985 before this Committee.

Finally, while FDA authority over irradiated food may not be changed by HR 696, what the FDA is **required** to do in its review for food safety is what will change. "Authority" is not the issue; what is required by law is the issue.

Lastly, we wish to take exception to food irradiation proponents citing of hospital sterilization by radiation of food for immuno compromised patients as proof of food safety. First, **food safety and sterilization are not synonymous.** Sterilization of food for terminally ill patients has nothing to do with concern for food nutrients. Sandra Aker, Chief Nutritionist at the Fred Hutchinson Memorial Cancer Center in Seattle, Washington, serves irradiated, sterilized, "regular appearing meals" to such patients only in the last week of their stay in order to stimulate their appetites. This comprises only about 2% of their total diet, as Ms. Aker said to me in Portland, Oregon in February, 1984, "We give them these sterilized meals just to get them to try to eat something, because we cannot release them until they indicate they will try to eat on their own. For the most part, they will take one or two nibbles and then we throw the rest away."

In conclusion, serving immunologically compromised patients and astronauts irradiated foods cannot be used to prove safety.

We urge very careful deliberations and examination of this bill and the whole concept of food irradiation. Thank you.

Sincerely,

Denis Mosgofian

Denis Mosgofian
Director and Co-Founder
National Coalition to Stop Food Irradiation

SANTA CRUZ CALIFORNIA PETITION 5,225 Signatures

Enclosures (10)

FOOTNOTES

1) Report of a Joint FAO/IAEA/WHO Expert Committee, Wholesomeness of Irradiated Food, WHO Technical Report Series 659

2) Welt, Martin A., Radiation Sterilization - A Contractor's Viewpoint, Radiation Technology, Inc., paper presented at 76th Annual American Society of Microbiology, Atlantic City, New Jersey, May 6, 1976, p. 13

3) Kosei, Takahashi, Irradiation of the Food We Eat, AMPO,Vol. 15, No. 2, 1983

4) Letter of December 4, 1985 from FDA's Dr. George Pauli to Ms. Ann Alberts on FOIA request F85-38054

5) Letter of October 31, 1985 from FDA's Hugh Cannon to Congressman Leon PAnetta.

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COLLEGE OF AGRICULTURAL AND
ENVIRONMENTAL SCIENCES
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DAVIS, CALIFORNIA 95616

March 5, 1985

Mr. Paul T. Libassi, Editor
The Sciences
The New York Academy of Sciences
Two East Sixty-Third Street
New York, NY 10021

Dear Mr. Libassi:

Bombarding Bananas - Zapping Zucchini was written, I believe, with the intention of providing readers with timely and balanced information regarding the possible uses of gamma radiation to extend the shelf life of food. Unfortunately, examples relating to the postharvest life of fruits and vegetables were inaccurate, misleading or totally wrong.

I can only believe that the authors were writing in a field (postharvest diseases of fruits and vegetables) in which they have little knowledge. For example, the authors comment upon the array of chemicals that might be applied after harvest to oranges. They later state that "if deemed safe by the FDA and then widely used by the food industry, irradiation could replace the fungicides and insecticides now sprayed on fruits and vegetables." It would be nice to be able to reduce our dependence upon fungicides. However, there is utterly no possibility that gamma radiation, as we now use it, could possibly replace fungicides. Instead, there is considerable evidence to indicate that certain diseases of harvested citrus fruits would be more active after irradiation. Radiation-induced cellular injury and the onset of senescence causes a reduction in the normal level of the commodity's disease resistance.

The late Dr. Edward Maxie and I concentrated on studies of the use of gamma radiation to control postharvest diseases of fruits and vegetables for 10 years (1963-1973) with support from the Atomic Energy Commission. We found that in citrus fruits, a dose of 200 krads was required to delay disease development by the pathogens Penicillium digitatum, P. italicum, or Geotrichum candidum. Diseases caused by Alternaria alternaria or Diplodia natalensis were often worse in irradiated than in non-irradiated citrus fruits. Partly that was so because the fruits calyx was weakened by irradiation to permit entrance into the fruit at the stem end.

Citrus fruits could not tolerate the 200 krad dose required for minimal suppression of disease fungi. After 200 krads and subsequent holding periods equivalent to the time required for transportation and marketing, the oranges (Navel and Valencia) exhibited the following: the albedo was abnormally soft, the fruit surface was often pitted, and the taste and aroma were noticeably different than unirradiated controls. Lemons irradiated before storage to reduce disease during storage suffered much more rot than the non-irradiated controls. Injury was

noted after storage in fruits irradiated with as little as 25 krads and severe injury was found in fruits that had been irradiated at 50 krads or higher. Further, citrus fruits are chilling sensitive and are damaged at refrigerated temperatures well above freezing. Irradiated fruit clearly exhibited increased susceptibility to the damaging effects of chilling injury.

A search of the literature of the past 25 years would have, at a minimum, alerted the authors that plant scientists had discovered serious problems with irradiation. Hatton, et al., recently reported that as little as 60 krads caused excessive injury in the form of scald and rind breakdown of grapefruit. Injury classed as moderate occurred at 15 and 30 krads but the authors judged those fruits to be acceptable. (T.T. Hatton, R.H. Cubbedge, L.A. Risse, P.W. Hale, D.H. Spalding, D. von Wideguth, and V. Chew. 1984. Phytotoxic responses of Florida grapefruit to low-dose irradiation. J. Amer. Soc. Hort. Sci. 109(5):607-610).

The authors also wrote "irradiation could reduce spoilage which now ruins an estimated 25 to 30% of the world's food supply. It would extend shelf life of products for weeks, increasing the length of time food could be stored or transported and still taste fresh, while decreasing the need for many of the chemical preservatives now used for this purpose." It is doubtful that any fresh (living) commodity's shelf life would be increased more than a few days by using irradiation to control rot organisms.

Quoting the authors further, "Irradiation is desirable not only because its effects are so lasting but because it 'cold-processes' food. This means that the gamma ray bombardment heats the food only slightly, minimizing adverse changes in color, odor, flavor, texture, and nutritional value. Thus, the technique is superior to both canning and freezing, which often leave food mushy, rubbery, or mealy." As a matter of fact, changes in color, odor, flavor, and texture are generally what one does complain about after fruits or vegetables are irradiated at doses that even minimally suppress postharvest pathogens. As for nutrition, the authors are evidently unaware that irradiation causes destruction of vitamin C.

Further on the authors said "the industry began to envision strawberries on fruit stands remaining bright red and firm for weeks." As a matter of fact, our experience showed that shelf life extention, from suppressing Botrytis cinerea, varied from essentially nothing to as high as 8 days. On average, however, there was generally an extension of 3 or 4 days. Some strawberry cultivars would not tolerate the 200 krads at all.

Sincerely,

Noel F. Sommer
Lecturer and Postharvest Pathologist
University of California, Davis

NFS:km

Infeasibility of Irradiating Fresh Fruits and Vegetables

E. C. Maxie, N. F. Sommer and F. G. Mitchell
University of California, Davis

Since World War II, the news media have occasionally carried stories claiming unusually long shelf lives for irradiated fruits and vegetables, often at room temperature. The biochemistry and physiology of senescence make these claims biologically absurd. True, an uncritical review of the "scientific" literature prior to 1964 might have led one to believe that irradiation had a commercial potential for a wide variety of commodities. Many studies were of questionable validity, however. Products were sealed in airtight containers, physiological state (maturity) was ignored, quality evaluation was ignored or at best subjective, sample size was inadequate for statistical treatment, dosimetry was not reliably determined, geometry of radiation distribution into the product seemed highly variable, pathological studies were not quantitative, and often not even qualitative, and experiments were stationary, precluding exposure of the commodity to the injury associated with transport and marketing. Our studies, in contrast, covering 15 years and designed to avoid these criticisms, have led us to conclude that irradiation has technical promise for but few commodities--and that economic feasibility reduces possible application even further.

Several reviews have been made of the historical and technical aspects of fruit and vegetable irradiation (1, 2, 4, 11, 13, 14, 15, 19, 20). This paper is concerned with the commercial feasibility of irradiating some major commodities.

Methodology

Two gamma-ray irradiators were used in these studies: A) the Mark II Cobalt-60 Experimental Food Irradiator (16), with a dose distribution of ±6% in the space containing the product; and B) the Portable Cesium (^{137}Ce) Irradiator, with a dose variation of ±12%. Dosimetry and dose distribution in the irradiators were determined by the Fricke (15, 17) ferric sulfate and copper sulfate methods. Product maturity, packaging, handling, and storage duplicated commercial conditions and practices. Cooling was by forced-air (6), ensuring rapid removal of field heat. Storage temperatures were near ideal for each commodity. Transit temperatures in test shipments varied slightly but were typical of commercial practices. Test shipments of strawberries were conducted via aircraft, railway cars, marine containers, and truck.

[1]Received for publication February 13, 1971.

Considerable public monies have been invested in research on irradiation of perishable commodities. Early optimistic reports were based on results with stationary tests. Extensive studies in California employing actual and simulated transit have yielded largely negative results. Conventional refrigeration is still the best means of reducing postharvest losses.

Nectarines, oranges, peaches, and tomatoes were shipped by truck. Other commodities were subjected to simulated-transit devices that closely duplicate the kind and severity of transit injury incurred in actual shipments (7). Commodity responses to irradiation under actual and simulated shipments were evaluated by teams of 3 persons, all with 5 or more years of experience in judging transit injury. Each commodity was subjected to a range of doses to establish approximate tolerances to irradiation. Where injury occurred at very low levels and/or where no technical benefit could be shown, no test shipments were made. A minimum of 3 experiments were conducted with triplicate samples of each treatment.

Results by commodity

Detailed results for each commodity would be too voluminous for presentation in this paper. Hence, Table 1 summarizes for all commodities the desired technical effect, estimated maximum tolerable dose, estimated minimum dose for a technical effect, and the phenomena judged limiting for commercial application.

Apples, avocados, bananas, cantaloupes, lemons, limes, mushrooms, oranges, pears, potatoes, and table grapes offer no promise for commercial irradiation, for alternative procedures are available that are cheaper, noninjurious, and more effective. Apricots, avocados, boysenberries, lemons, limes, nectarines, peaches, pears, table grapes, and tomatoes can be dismissed because radiation injury is excessive. Asparagus is too small an industry, and the harvest season too short, for an economic irradiation operation.

Strawberries are the only domestic commodity with even a remote potential for commercial irradiation. Laboratory and simulated transit studies (9) had shown the 'Shasta' cultivar to tolerate doses of 200 Krad without excessive harm to berry quality or vitamin content. During 1970, 5 test shipments were conducted by transcontinental truck, and 2 by marine carrier. As shown in Table 2, only 1 shipment showed a commercially acceptable benefit on arrival (marine test 1). In all other tests, the sum of injured and decayed fruit raised the percentage of unmarketable fruit in the irradiated lots almost to the level in nonirradiated lots. When the fruits were stored for 48-72 hr after arrival to simulate retail marketing, irradiation at both 150 and 235 Krad showed a favorable effect on the percentage of marketable fruit in truck test 4 and marine test 1. Even so, the amount of unmarketable fruit in the irradiated lots was high enough to depress the price if the berries has been offered for sale.

Of the 20 species listed in Table 1, only the papaya shows appreciable technical promise for irradiation. In studies conducted by the University of Hawaii and the Hawaii Department of Agricultural (in which we played a minor cooperative role), the quality was excellent in papayas subjected to doses that sexually sterilize the Hawaiian fruit fly.

Is irradiation feasible?

Induced radioactivity, loss of nutritive value, or radiological production of harmful substances in the product were initially considered to be the most likely limitations to the irradiation of foodstuffs (1, 2). These fears have been reliably dispelled (2, 8, 21). At the same time, with most fruits and vegetables, irradiation is infeasible because of: A) lack of a beneficial effect at noninjurious doses; and B) unfavorable economics in relation to competing processes.

For irradiation to be practical with any commodity, the host must have a considerably higher tolerance to radiation than the deteriorative organisms or systems needing control. Few commodities have that required differential tolerance (Table 1). Defining tolerable doses precisely is difficult because preharvest conditions may effect postharvest response to stress. Similarly, defining a precise dose for effective inhibition of rot under commercial conditions is virtually impossible.

The minimum effective dose depends upon the extent of fungus invasion at the time of irradiation and the degree of control required. Well developed lesions may require a much higher dose than new, tiny lesions (19, 20). With the gray mold disease caused by *Botrytis cinerea* Pers for example, a 200 Krad dose delays disease development for 3-5 days at 5°C. With strawberries, such a delay may be highly beneficial. With grapes destined for

Page 203 not submitted.

Table 2. Effect of gamma-irradiation of transit injury, decay, and marketability of 'Shasta' strawberries in commercial truck and marine shipments.[7]

Test no.	Destination	Dose in Krads	Injury scores[8]	% decayed fruit		% unmarketable fruit	
				On arrival	+ 3 days' storage	On arrival	+ 3 days' storage
1	Minneapolis	0	1.6	1.6	4.4	5.5	9.8
		150	1.8	1.8	2.5	8.3	8.4
		235	1.8	1.1	2.1	8.5	8.8
2	Atlanta	0	1.8	4.6	11.1	6.4	13.2
		150	2.0	1.8	4.9	4.3	6.8
		235	1.9	1.7	6.4	5.2	10.0
3	Atlanta	0	1.9	11.5	9.5	14.7	12.5
		150	1.8	7.4	8.4	11.6	13.4
		235	2.0	5.3	5.5	8.9	13.5
4	Atlanta	0	1.3	12.9	54.1	15.4	54.5
		150	1.5	4.1	14.5	8.4	18.3
		235	1.5	3.9	10.1	7.3	12.9
5	Atlanta	0	2.0	1.7	12.1	5.6	14.2
		150	2.1	0.7	2.9	4.7	7.0
		235	2.1	0.9	2.7	5.2	10.3
6	Honolulu	0	1.0	49.4	80.3	50.2	80.3
		150	1.6	5.6	8.9	7.4	16.4
		235	1.7	6.9	6.4	10.1	10.0
7	Honolulu	0	1.6	1.6	6.3	4.4	14.8
		150	1.5	0.9	0.9	2.9	14.8
		235	1.4	1.1	0.9	4.9	14.8

[7]Shipments to Minneapolis and Atlanta, 4 days by refrigerated truck; to Honolulu, 9 days by refrigerated container.

[8]Scored on a numerical 0-5 scale; 0 = no injury, 5 = unmarketable. Fruits were scored individually, and weighted average calculated.

must decline from present accomplishments before irradiation could be profitable for the California industry. In 1955, transit losses averaged 25%, almost all attributable to decay. Irradiation at 200 Krad would have substantially reduced those losses of 15 years ago without an unacceptable increase in transit damage. Today, however, our test shipments indicate that in most cases current losses of strawberries are less than 10%, though no reliable estimates of commercial losses are available. This improvement in maintenance of berry condition in recent years can be attributed to: A) introduction of firmer cultivars such as 'Tioga'; B) use of plastic sheets underneath growing plants, thus protecting the fruits from contact with the soil; C) carefully trained and supervised pickers; D) protection of harvested fruit in the field from direct sunlight, with prompt transport to the cooling plant; E) use of forced-air cooling to remove field heat quickly; F) adoption of trucks instead of railcars as carrier vehicles, cutting transit times approximately in half; and G) use of air-suspension systems on transcontinental trucks, thereby reducing transit injury. If the industry only maintains these practices, irradiation would not be economically feasible. It should be noted that in the United States only in California is the strawberry season long enough for irradiation to be potentially economical.

Many commodities are not covered in this report, but the diversity of species studied and the negative results obtained indicate that irradiation holds little promise for perishable commodities.

Occasionally, irradiation is suggested as a promising technology for developing countries as a substitute for refrigeration (3). This hope should be dispelled with respect to controlling rot or senescence in fruits and vegetables. Irradiation cannot substitute for refrigeration, and at best could only supplement it. Thus, nations with limited funds should first invest in conventional refrigerated storages and transport vehicles. Good temperature management is applicable to all commodities; irradiation to only a few.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Washington DC 20204

December 4, 1985

Ms. Ann Alberts
Box 5183
Santo Cruz, CA 95063

Re: F85-38054

Dear Ms. Alberts:

This is in response to your freedom of information request, referenced above, in which you ask a number of questions.

You requested a list of all food or spice irradiation facilities or companies in the US as well as such a list of such facilities in Mr. Deighton's district.

FDA has not compiled a list of radiation facilities or companies in the US that treat food. Companies treating food need not register with the FDA. Although we know of a number of radiation processing facilities, we have no list concerning which of these facilities have treated food.

We have no list of all the foods or spices that get irradiated or of the number of pounds of such food irradiated per year.

Inspection frequency can vary depending on the district, the type of food processing facility, and whether a problem is anticipated. FDA develops plans each year to target its resources at the most serious potential problems while maintaining a surveillance on the food industry as a whole. Therefore I cannot say in specific terms the frequency with which a facility is visited. However, I am enclosing a copy of an article on inspection that was published in the FDA Consumer magazine.

Companies using irradiated spices or other foods are not required to report this fact to FDA. We have not attempted to compile such a list.

An "incidental additive" is a substance that is not intentionally added to food as an ingredient but may become a component of food because of its intended use. The most common examples are the components of packaging materials that may migrate to food during storage.

Page 2 - Ms. Ann Alberts

Finally, regarding labelling, FDA regulations require that a food that has been irradiated must bear a statement "treated with ionizing (or electron, or gamma) radiation." FDA has interpreted that regulation to apply only to a food that has been irradiated, not to a food that contains an irradiated ingredient.

There will be no charge for this request because the records you requested do not exist.

Sincerely yours,

George H. Pauli, Ph.D.
Division of Food and
Color Additives, HFF-330
Center for Safety and
Applied Nutrition

SIERRA CLUB MARIN GROUP

October 17, 1985

Att: Monique Israel

Marin Chapter for Coalition
to Stop Food Irradiation

I am sure you will be pleased to know that the Executive and Conservation Committees of the San Francisco Bay Chapter, Sierra Club, have approved a two-part resolution, which I summarize as follows:

1. To urge the National Club to take a position that no gamma irradiation of food products be permitted until further and adequate research has been completed.
2. To urge local jurisdictions to pass ordinances requiring that all gamma-irradiated food be clearly so labelled or noticed at point of sale.

If you refer to this action be careful to distinguish the two parts. The first involves the national issue on which the Chapter cannot take the initiative in establishing a policy. The second is a local matter within the purview of the Chapter, I.e., for the Bay Area.

If you have questions, please call me.

Glenn Metzger
7 Crest Road
Fairfax CA 94930
456-6944

"We shall require a new manner of thinking if mankind is to survive." —Albert Einstein

million in U.S. government research and development programs. This investment has made the difference between continuation of some of these programs and their cancellation. Bilateral cooperation in the nuclear field (fission and fusion) is particularly heavy, both in terms of Japanese investment in the United States and the intensity of the technical exchanges, and most other fields of science and engineering are covered. The overall relationship is unique among nations. It could be dismantled much more easily than it was created.

Goland is to be applauded for making his views known. If more of the many hundreds of American scientists and engineers who have been participants in cooperative or joint programs with their Japanese counterparts were to speak up in like fashion, the tide of intellectual protectionism could be dammed.

JUSTIN L. BLOOM
Technology International, Inc., 11600 Georgetowne Court, Potomac, Maryland 20854

Student Scientific Conferences

A scientific meeting of poster papers presented only by students can provide a simple and remarkably effective way of stimulating scientific interaction and building personal contacts among students from different schools and academic departments who have related scientific and technical interests.

We recently organized such a student-only scientific conference for students working on or with lasers and related optical topics in the San Francisco Bay area. The meeting was held in a public area of the Terman Engineering Building on a Saturday afternoon. Invitations to participate were sent a few months in advance to graduate and undergraduate students in relevant academic departments in colleges and universities in the northern California area. Participants were invited to present a poster paper according to the usual rules; that is, we simply provided a space about 1 meter high and 1.5 meters wide on which illustrations and text could be thumbtacked.

Anyone could attend the meeting, and invitations were distributed to industry through the local chapters of various professional societies. However, only students could submit posters. In addition, a program booklet containing short abstracts supplied by each contributor was distributed at the meeting.

In the final event, there were approximately 40 papers from seven different schools, with department affiliations ranging from physics, chemistry, and biology through electrical, mechanical, and aeronautical engineering. The interaction among the attending students was clearly successful, with animated conversations continuing around individual posters from the time the meeting opened until it closed some 3 hours later. One technique that seemed particularly effective was to place posters that appeared to have related technical content, but were from different schools or departments, in close proximity to each other. This stimulated many fruitful contacts among students who were previously unaware of each other's existence.

There are obviously many other topics or themes around which such meetings could be organized. One interesting observation was that a sizable number of the better-presented posters did not contain the name and department of the student presenting the poster. Does ego development only occur later on in the graduate education process?

P. M. FAUCHET
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Irradiation of Foods

While recognizing the induction of poorly characterized "unique by-products" in foods after high-energy irradiation, Marjorie Sun (News and Comment, 17 Feb., p. 667) implies that there is no way in which concentrated doses of such products could be evaluated toxicologically in a manner analogous to high-dose carcinogenicity or teratogenicity testing. This is certainly not the case. Stable radiolytic products could be extracted from irradiated food by various aqueous and nonaqueous solvents, which could then be concentrated and subsequently tested. Until such fundamental studies are undertaken, there is little scientific basis for accepting industry's assurances of safety. Similarly, there is little or no basis for accepting Food and Drug Administration (FDA) approval of irradiation as an alternative to ethylene dibromide (EDB) fumigation, let alone for more large-scale use.

These considerations are yet further emphasized by Department of Health and Human Services Secretary Margaret Heckler's support of the industry position in her arbitrary rejection of the FDA's proposal for labeling of radiated food. They are also emphasized by the availability of known safe alternatives to EDB, including aluminum phosphide for grains and cold storage for fruits and vegetables. Public policy on the nation's foods must not be based on reckless gambles and denial of the public's right to basic information and free choice.

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Department of Preventive Medicine and Community Health, University of Illinois Medical Center, Box 6998, Chicago 60680
JOHN W. GOFMAN
Donner Laboratory of Medical Physics, University of California, Berkeley 94720

According to a special FDA committee assigned to review food irradiation, radiolytic products are difficult to pinpoint because they are of unknown composition and must be extracted from foodstuffs, which are inherently chemically complex. This committee, formed in 1979 under the Carter Administration, reviewed available studies and concluded that food irradiated at the proposed standard of 100 kilorads contains "a concentration of total radiolytic products in food so low that it is nearly impossible to detect with current techniques."

The Environmental Protection Agency does consider aluminum phosphide to be a suitable alternative to EDB. Agency documents note, however, that aluminum phosphide is explosive and acutely toxic and poses a risk to unprotected applicators.—MARJORIE SUN

Marjorie Sun quotes one of us (D.S.) as saying there was nothing wrong with irradiated food. In fact, as Sun hints, the Center for Science in the Public Interest has not investigated this matter and has never adopted an official position.

MICHAEL F. JACOBSON
DEBORAH M. SCHECHTER
Center for Science in the Public Interest, 1755 S Street, NW, Washington, D.C. 20009

Erratum: In the report "Communal nursing in Mexican free-tailed bat maternity colonies" by G. F. McCracken (9 Mar., p. 1090), table 1 was incorrectly printed. The correct table is reprinted below.

Table 1. Nonrandom nursing in 167 pairs of *Tadarida brasiliensis mexicana*. $P < 0.001$ (G-test).

Result	Nonparental genotype pairs		
	ME	SOD	Both loci
Expected (random)	24.3	21.3	42.5*
Observed	5	2	*

*Factors out nonparental combinations that could be observed at both loci

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PATHOMORPHOLOGY OF THE KIDNEYS IN RATS AFTER PROLONGED INGESTION OF IRRADIATED FOODS

A. I. Levina and A. E. Ivanov

UDC 616.61-091-092.9-02:612.392.014.482.4

Structural changes of membranous-proliferative glomerulonephritis type, possible autoimmune in character, were shown to develop in the kidneys of rats fed for a long time with food irradiated with γ rays. The severity of the disturbances depends on the dose of irradiation of the foods.

KEY WORDS: kidney; effect of irradiated food; γ rays.

In many countries nowadays certain foodstuffs are irradiated with γ rays to lengthen their storage life. Conflicting views have developed regarding the consequences of this method of preservation. In particular, some workers consider that the prolonged ingestion of food consisting even in part of irradiated products can lead to definite functional and structural disturbances [2-6, 12-18].

The object of this investigation was a morphological study of various organs and tissues of noninbred albino rats fed for 20 months solely on irradiated food, in order to obtain a clearer idea of the after-effects of feeding with irradiated foodstuffs.

EXPERIMENTAL METHOD

Experiments were carried out on 240 rats of both sexes used at the age of 1 month. The animals were divided into four groups, with 30 males and 30 females in each group, and were kept on the ordinary animal house diet, as drawn up for research institutes by decree of the Ministry of Health of the USSR dated March 10, 1966. The animals of group 1 received food irradiated on the K-300 γ ray apparatus in doses 10 times higher than the optimal doses for preservation (0.25-5.6 Mrad). The rats of group 2 received food irradiated in optimal doses (25-500 rad) and those of group 3 received food irradiated in doses of one tenth the optimal level (2.5-56 krad). The animals of group 4 (control) were kept on a natural diet. The progeny of these rats (240) ate irradiated foods for a correspondingly shorter time (14 months) than their parents. At the end of the experiment all the animals (306) were decapitated for pathological examination. The kidneys were fixed in 10% neutral formalin solution and paraffin sections were stained with hematoxylin–eosin, picrofuchsin, and Schiff's reagent with amylase control. In sections cut on a freezing microtome the distribution of lipids was determined by staining with Scharlach red, and acid and alkaline phosphatase activity was determined by the azo-coupling method. By means of a special grid [1] the number of glomeruli per field of vision and the number of nuclei in the glomeruli were counted; the ratio between the area of a renal corpuscle and glomerulus was determined, and by means of an ocular micrometer the thickness of the membranes of the glomerular capillaries and layers of the capsule was measured. The results were subjected to statistical analysis.

EXPERIMENTAL RESULTS

In all the experimental animals regardless of the type of food the kidneys were flabby in consistency and slightly livid in color compared with those of the control rats. Microscopic investigation showed irregular thickening and loosening of the fibers of the basement membranes of the capillaries and of both layers of the capsule of the glomeruli on account of the accumulation of PAS-positive substances (1 μ in the control, 5–10 μ in the experiment), an increase in the number of nuclei in the glomeruli, the presence of serous fluid in the lumen of the capsule, and a shift in the ratio between the area of the renal corpuscle and the glomerulus (Fig. 1A).

Laboratory of Pathomorphology, Institute of Transplantation of Organs and Tissues, Ministry of Health of the USSR, Moscow. (Presented by Academician of the Academy of Medical Sciences of the USSR A. P. Avtsyn.) Translated from Byulleten' Éksperimental'noi Biologii i Meditsiny, Vol. 85, No. 2, pp. 230-232, February, 1978. Original article submitted September 9, 1977.

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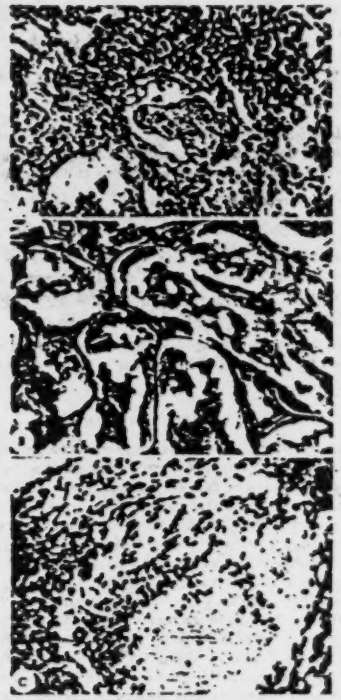

Fig. 1. Kidneys of rat after prolonged ingestion of foods irradiated in doses of 25-500 krad (group 2). A) Membranous-proliferative glomerulitis, infiltration of stroma with lymphocytes and histiocytes, cloudy swelling and intracellular edema of epithelium of convoluted tubules. Hematoxylin–eosin, 140 ×; B) necrosis and necrobiotic changes in epithelium of convoluted tubules. Hematoxylin, 280×; C) fibrinoid necrosis of arterial wall in zone of infiltration by lymphocytes, histiocytes, and eosinophils. Hematoxylin–eosin, 140×.

In the convoluted and straight tubules marked degenerative changes were found in the epithelium with thickening of the basement membranes; in the proximal portions of the tubules cloudy swelling was the predominant change, whereas in the distal portions it was intracellular edema combined with severe necrobiotic disturbances and death of the epithelium (Fig. 1B). In the straight tubules signs of cloudy swelling and fatty degeneration, with tiny intracellular lipid droplets, desquamation of the epithelium, the presence of hyaline casts, and tiny particles of lime in the cytoplasm of the epithelium with the formation of calcified casts were observed. The interstitial tissue was always infiltrated by lymphocytes and histiocytes, together with a few eosinophils and

neutrophils, the collagen fibers were coarser and more numerous, the content of PAS-positive materials in the ground substance was increased, the thickness of the walls of the small arteries was increased on account of permeation with PAS-positive materials, and alkaline phosphatase activity was increased.

However, the severity of these changes was directly dependent on the dose of irradiation of the food products. For instance, in animals eating food irradiated in a dose of 0.25-5.6 Mrad the severest degenerative and necrobiotic changes were observed, and the number of cells in the glomeruli was sharply increased. Sclerosis of the stroma was more marked, and for that reason the number of glomeruli per field of vision was reduced compared with the control to a statistically significant degree. Vessels of the juxtamedullary zone (Fig. 1C) showed changes of the periarteritis nodosa type. In animals consuming food irradiated in a dose of 2.5-560 krad, the sclerotic changes developed more slowly, the response was mainly cellular with, in particular, infiltration by eosinophils, and small interstitial hemorrhages were observed. The number of glomeruli per field of vision in these rats was increased ($P < 0.05$).

Investigation of the kidneys of the offspring of the rats showed similar changes with the same dependence of their severity on the dose of irradiation of the foodstuffs. The only difference was that the structural changes in the testes were less marked in the progeny than in their parents. For example, in the animals of group 1 the thickness of the basement membrane reached 10 μ, but only 6 μ in their offspring, and severe necrobiotic changes of the epithelial cells of the convoluted tubules were hardly observed.

Prolonged feeding with irradiated food thus causes changes of the membranous-proliferative glomerulitis type in the kidneys, with infiltration of the interstitial tissue with lymphocytes, histiocytes, and eosinophils, accumulation of PAS-positive substances in the mesangium, capillary membranes, and walls of the blood vessels, and with cloudy swelling of the tubular epithelium. Morphological changes of this type are known to be characteristic of autoimmune processes in the kidneys [8-11]. Furthermore, the work of Kuzin [7] and his collaborators has shown that substances (radiotoxins) formed in irradiated cells and tissues can simulate the action of radiation, including the development of postradiation sterility. It can therefore be suggested that these elements of the irradiated foods form antigenic complexes with the body proteins, which react with the corresponding antibodies on the basement membranes of the renal glomeruli; the results of the observations showed, moreover, that in this case the reaction between autoantigen and autoantibody can also develop in other organs, notably the testes.

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PATHOMORPHOLOGICAL CHANGES IN THE TESTES OF RATS FED ON PRODUCTS IRRADIATED WITH γ RAYS

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KEY WORDS: rat testes; γ rays.

Information on the harmful effects of prolonged consumption of products preserved by exposure to γ rays has accumulated in the Soviet and western literature. In particular, it has been shown that prolonged feeding with irradiated meat and fish causes disturbances of protein and lipid metabolism, a decrease in the rate of gain of body weight, and a decrease in the number of offspring in experimental animals [2]. Previously [1] the writers described significant morphological changes of the membranous glomerulonephritis type in the kidneys of rats fed for 20 months with irradiated products.

This paper describes the results of a morphological study of the testes of the same animals.

EXPERIMENTAL METHOD

Experiments were carried out on 120 mature male rats aged 1 month kept in all experiments together with the same number of females. The animals of group 1 received the standard animal house diet [1], irradiated in a dose 10 times higher than the optimal dose used in practice for food preservation (0.25-5.6 megarads). The animals of group 2 received food products irradiated in the optimal dose of 25-500 kilorads, and the food given to animals of group 3 was irradiated in a dose one-tenth as high as in group 2 (2.5-56 kilorads). The rats of group 4 (control) received identical food products, but not exposed to γ rays. The food products were irradiated on the K-300 (All-Union Food Conservation Research Institute) γ-ray apparatus with cobalt-60.

All the animals were decapitated 20 months later. The testes were weighed on analytical scales, fixed in neutral 10% formalin, and sections were cut and stained with hematoxylin–eosin, by Masson's method, with Scharlach red, methyl green–pyronine, and by the PAS reaction. To study the dynamics of spermatogenesis, the frequency of discovery of stages of the cycle in the spermatogenic epithelium (CSE) was determined in sections. The numerical data were subjected to statistical analysis.

EXPERIMENTAL RESULTS

The coefficient of variation of the absolute weight of the testes in animals receiving food irradiated in doses of 0.25-5.6 megarads (group 1) and 25-500 kilorads (group 2) was significantly higher than normally. A marked difference was observed in the size and weight of the right and left testes, which could be either increased (up to 2.7 g) or reduced (down to 0.5 g). However, the difference between the ratio of the weight of the larger testis to the weight of the smaller testis was significant only for the males of group 1 ($P < 0.05$), fed with products irradiated in a dose 10 times higher than optimal. Meanwhile, edema of the stroma was observed microscopically in animals of all three experimental groups to a varied degree, accompanied by a high content of PAS-positive substances, enlargement and coarsening of the collagen fibers and, in a few cases, accumulation of labrocytes. Collections of lym-

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phoid cells with pyroninophilic cytoplasm were found in the interstitial tissue and tunica albuginea of nearly all testes. The walls of the blood vessels appeared edematous, with separation of the fibers of the basement membranes and with a high concentration of PAS-positive substances in the subendothelial layer. The basement membranes of the seminiferous tubules also were loosened in structure and thickened because of permeation by PAS-positive substances. Most cells of the spermatogenic epithelium had pycnotic nuclei and contained droplets of fat in their cytoplasm (Fig. 1). Spermatogonia, multinuclear spermatids, and Sertoli cells were preserved in some tubules. Spermatogenic cells were absent from individual tubules. The walls of these tubules were sclerotic and thickened, their diameter was reduced by half to two-thirds, and their lumen was packed with proliferating Sertoli cells with a high content of fat in their cytoplasm. The changes described above were found in 88.2 ± 5.16% of tubules in the animals of group 1, in 41.1 ± 2.44% in group 2, and in 54.4 ± 3.1% in group 3, whereas in the control they were observed in only 11.6 ± 0.48% of tubules.

Regions 0.5-0.8 cm in diameter, yellowish in color with dark red patches, could be distinguished macroscopically in the enlarged testes (1.9-2.7 g). Microscopically it could be seen that these regions consisted of an extensive accumulation of glandulocytes (Leydig cells) (Fig. 2), containing large droplets of fat, among which atrophic tubules, packed with PAS-positive material, and also hemorrhages with clumps of hemosiderin could be distinguished. In the reduced testes, on the other hand, the most conspicuous features were absence of spermatogenesis in the tubules and coarse, sclerotic changes in the interstitial tissue. In addition, small groups of proliferating Leydig cells and foci of coagulation necrosis of the tubular epithelium were found in all testes.

Extensive areas of proliferation of Leydig cells, signs of aspermatogenesis, and coagulation necrosis were observed most frequently in the animals of groups 1 and 2 — in 27.5 ± 6.0 and 13.9 ± 2.1%, respectively, much less often in the rats of group 3 (8.4 ± 1.98%), and not at all in the control.

There was also a significant difference ($P < 0.05$) from the control in the frequency of discovery of the stages of CSE in the sections and, consequently, in their duration. Shortening of the X stage and lengthening of all other stages except the first were noted in the rats of group 1, shortening of stages VIII, X, and XI and lengthening of stages II, V, VII, and XII in group 2, and shortening of stages V, VI, X, and XIII and lengthening of stages II, IV, IX, and XII of CSE in group 3.

The experiments thus showed that three types of morphological changes arise in the testes as a result of prolonged feeding of rats with irradiated products: trophic disturbances, amounting in some cases to coagulation necrosis and aspermatogenesis; compensatory adaptive changes with the formation of large, nodular foci of proliferation of glandulocytes; disturbances of the dynamics of spermatogenesis.

Judging from these morphological observations, the structures first affected were those forming the blood–testes barrier, and later morphological changes were found in the spermatogenic epithelium. This corresponds to the pattern of autoimmune changes in the testes [4, 6]. At the same time, it is noteworthy that the structural changes observed were similar in many respects to those arising in the testes during prolonged exposure to radiation [5]. This similarity evidently is not fortuitous, but is due to the common nature of the initial biochemical factors producing responses of the animal, similar in their final effect, to prolonged feeding with irradiated products and after chronic irradiation. Radiotoxic substances capable of simulating the action of radiation on the body may be formed in irradiated cells and tissues of plant and animal origin [3]. It can therefore be suggested that prolonged entry of such substances into the body in the composition of irradiated food may give rise to morphological changes in the testes, as also in other organs [1], similar to the after-effects of chronic irradiation. This hypothesis is confirmed by the direct dose dependence established between the severity of the structural changes in the testes and the dose of irradiation of the foods consumed. As regards compensatory and adaptive changes, in the form of proliferation of glandulocytes, these may be connected with a reduction in production of the hormone "inhibin" as a result of trophic disturbances in cells of the tubular epithelium [7, 8].

Fig. 1

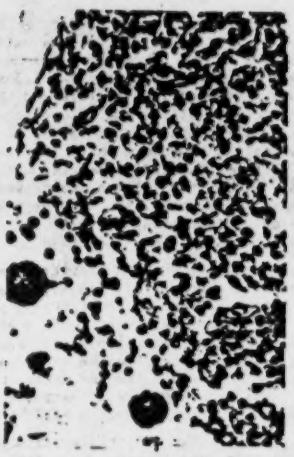

Fig. 2

Fig. 1. Infiltration of stroma, its permeation with PAS-positive material, and degenerative changes in the spermatogenic epithelium (rat of group 2). PAS reaction, 140×.

Fig. 2. Accumulation of Leydig cells, epithelium of neighboring tubule thickened, spermatogonia, Sertoli cells, and multinuclear spermatids visible (rat of group 2). Hematoxylin–eosin, magnification: objective 20, [ocular not specified].

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1) INTRODUCTION

Radiation can be used to:

* delay ripening of fruits
* prevent sprouting of vegetables
* kill insect pests
* reduce or eliminate microorganisms that cause food to spoil

It is claimed that irradiation can produce a number of other improvements in food.

The process is currently banned in Britain (with the exception of sterile diets for transplant patients) but permitted by some other countries. There are strong pressures to permit its use here also.

This report explains the process and the issues that concern consumers, workers in the food industry and people involved in food policy, public health and environmental protection.

It argues that simple assurances by experts that the process is safe are not enough. A full public debate on all the issues surrounding food irradiation is needed, including:-

- o wholesomeness of irradiated foods - food quality, nutrition losses, chemical and other changes in irradiated foods.
- o consumers rights to information about irradiated foods.
- o health and safety of food industry workers.
- o the economics of irradiation - food prices, changes in patterns of employment, environmental impacts.
- o regulation and monitoring of food irradiation and imported irradiated foods.
- • the consequences (health, decontamination costs, actual + probable + possible in human life, disease, and in dollars.)
- • the alternatives, including the exploration of organic growing, farm direct marketing, small scale and regionally distributed local needs based agriculture

A BRIEF HISTORY OF FOOD IRRADIATION

The idea of irradiating food is not new. The treatment was tested on strawberries in Sweden in 1916. The first patents on the idea were taken out in the US in 1921, and in France in 1930. Little progress was made until 1953 when US president Eisenhower announced the "Atoms for Peace Programme". Public attention was to be shifted away from nuclear weapons by promoting nuclear power and other uses of nuclear technology, so that the academic and industrial infrastructure could be developed behind which the weapons programmme would continue. There followed a decade of intensive research into food irradiation funded and supervised by the US Department of Defence. (1)(2)

The first commercial use of food irradiation actually occured in Germany in 1957 for sterilisation of spices used in sausage manufacture. This was brought to an abrupt end when the German government banned the process in 1958. The Soviet Union was the first government to permit irradiation; for inhibiting sprouting of potatoes in 1958, and de-infestation of grain in 1959. Canada permitted its use for potatoes in 1960. The US Food, Drug and Cosmetics Act of 1958 defined the irradiation process as an additive. Users have to petition the US Food and Drug Administration for permission to market irradiated products. This has resulted in stringent requirements for testing of irradiated foods in the US. It was not until 1963 that clearance was given for sterilisation of can-packed bacon and the inhibition of potato sprouting and wheat disinfestation already in use elsewhere. The clearance on bacon was withdrawn in 1968 after a review of the research found adverse effects and deficiencies in the conduct of the experiments. (29)

Since then 21 countries have permitted irradiation of 28 different foodstuffs for public consumption. Commercial activities are planned in a further 11 countries as of January 1985. (73)

Britain, along with West Germany, currently does not permit irradiation of food for public consumption. (7) There does exist the mechanism for government to permit its use under the Food (Control of Irradiation) Regulations 1972 (8) subject only to approval of the facilities and the system for recording doses administered to the food. So far these regulations have only been used for irradiation of food for hospital patients needing sterile diets, such as transplant patients, and a few public relations exercises. Some 800 tons of animal feed, mainly for experimental animals has also been irradiated. (1)

This may soon change as a result of the report of the UK government's Advisory Committee on Irradiated and Novel Foods, (9) and with the growing pressures for harmonisation of national legislation within the countries of the EEC. (10)

Table 1: FOODS IRRADIATED IN OTHER COUNTRIES.

Foods	Argentine	Bangladesh	Belgium	Canada	Chile	Denmark	France	Hungary	Israel	Italy	Japan	Netherlands	Norway	Philippines	Poland	South Africa	Spain	Thailand	Uruguay	USA	USSR
Potatoes	x	x	x	x	x	x	x		x	x	x	x		x	x	x	x		x	x	x
Onions		x	x	x	x		x	x	x	x		x			x	x	x	x			x
Garlic			x				x			x						x					
Shallots			x				x														
Wheat and other grains		x		x	x							x								x	x
Spices		x	x		x		x	x				x	x							x	
Chicken		x			x				x			x				x					
Fish		x			x							x									
Frozen shrimps		x										x									
Froglegs		x										x									
Ryebread												x									
Egg powder												x									
Blood proteins												x									
Cocoa beans					x							x									
Dates					x																
Pulses		x			x																
Pawpaw		x			x											x					
Mango		x			x											x					
Strawberries			x		x							x				x					
Paprika			x																		
Mango achar																x					
Bananas																x					
Dry food concentrate																				x	
Dried fruits																				x	
Mushrooms											x										
Endive											x										
Asparagus											x										
Battermix											x										

The mixture of protective and permissive national regulations clearly acts as a barrier to international trade in irradiated food products which food processors would like to see removed. After a series of seminars organised through the International Atomic Energy Agency, (3) a Joint Expert Committee of the IAEA, the World Health Organisation and the Food and Agriculture Organisation of the United Nations was set up in 1971. This WHO/IAEA/FAO committee was given the task of reviewing and guiding the research into issues of concern. It has produced key reports in 1976 (4) and 1980. (5) on "The Wholesomeness of Irradiated Foods". At the same time The Codex Alimentarius Committee of the UN has formulated International Guidelines on irradiated foods based on the recommendations of this joint committee. (6)

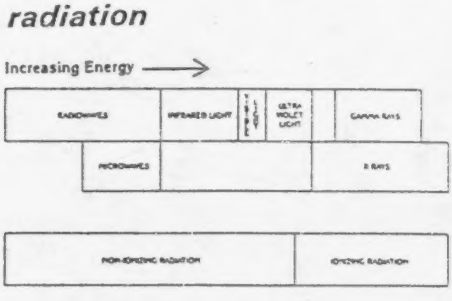
2 - WHAT IS FOOD IRRADIATION?

Very simply it is a treatment involving very large doses of ionising radiation to produce some desired changes in food particularly those allowing longer storage or 'shelf life.' This section covers the nature of radiation and what it does, the types of irradiation plant, radioactive sources used, the doses involved and the question on everyone's mind - can food become radioactive?

IONISING RADIATION

Radiation is a household word that covers a wide spectrum of energy. At the low end of the spectrum are the emissions from power lines and visual display units. Higher up are radiowaves and microwaves. Also included are infra red, visible and ultra-violet light, and at the upper end are found x rays, and gamma rays from radioactive material.

When radiation strikes other material it transfers its energy. This energy transfer can cause heating, as with microwave cooking, or lying in the sunshine. Above a certain level however the radiation has sufficient energy to knock electrons out of the atoms of the material bombarded. This can break the molecular structure of the material, leaving positively and negatively charged particles called ions. Above this level the radiation is called ionising radiation.



(11)

The ions are chemically very active and easily recombine or initiate chemical reactions with surrounding material.

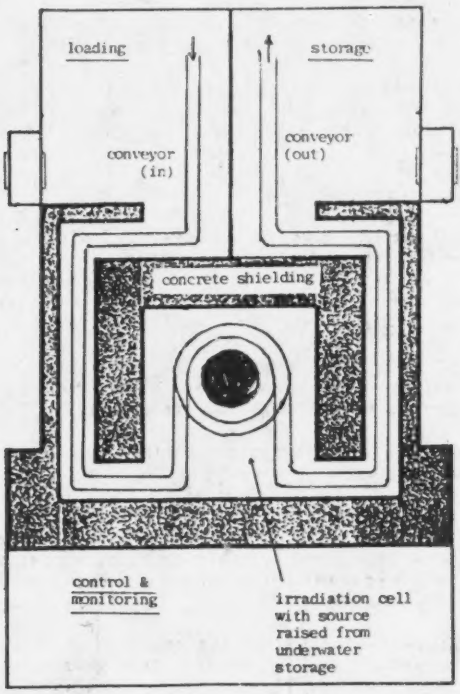
Thus ionising radiation alters the chemical structure of material. This in turn can have biological effects on the behaviour of living organisms and the materials they feed on. (12)

Some of the biological effects in irradiation of food can be considered desirable. Irradiation of **living** organisms, especially people, is almost always damaging. (13)(14)(15)

FOOD IRRADIATION PLANT

There are currently some 30 planned or operating food irradiation facilities worldwide. (1)(73) There are ten plants in Britain which currently irradiate medical supplies or animal feed. Of these only four, all owned by ISOTRON Ltd, will be able to handle commercial food irradiation. One other may be able to do so and privatisation of some hospital facilities might open possibilties for others on a small scale. (61) (72)

LAYOUT OF AN IRRADIATION PLANT



In general an irradiation facility consists of:

- **a loading facility** - where the food to be irradiated is packaged, and pre-treated by heating and/or refrigeration as needed and loaded onto conveyors that will carry it to:

- **the irradiation cell** - where food is exposed to the radiation source. This can be either a cobalt or caesium gamma ray source or an x ray or electron beam machine source. The distance the food passes from the source and the length of time it is exposed will determine the dose that the food receives. The size of the batch will control the extent to which the food is uniformly exposed or whether there will be large differences between maximum and minimum doses to different parts of the food batch. Thick concrete shielding protects workers from direct exposure to the source. It then passes into -

- **a storage facility** where it is removed from the conveyor and stored at the required (usually low) temperatures before being despatched to long term storage or retailing outlets.

In addition the plant needs:

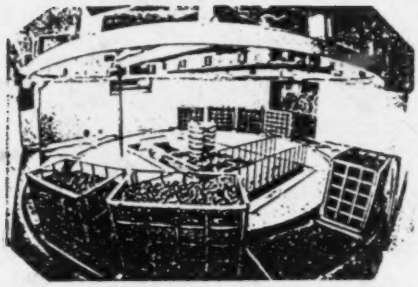
- **a fuel handling unit** where irradiated radioactive sources in the form of sealed rods or strips of cobalt 60 or caesium 137 are received and loaded by remote handling into the irradiator. They are usually stored underwater and raised from this into the irradiation cell to expose the food.

- **a control unit** governs the movement of the food (and the radioactive sources) through the irradiator.

- there are also facilities for monitoring doses to the food and keeping records.

Since there is no way of detecting that food has been irradiated, or how many times and with what doses, it is vital that strict control is maintained at the source of irradiation and that appropriate certification of the doses given accompanies the food thereafter.

The shape of the irradiation cell, and the siting of the radioactive sources, and the path of the food through the cell depends on the type of food being irradiated. Some types of irradiator use a central source and pass the food around it on one of a number of circular tracks.



Potato Irradiator (Japan) (1)

Some foods such as fish may pass along a tube or between two parallel sources. There are proposals for low level irradiators for use on board ships. The plan is to then further irradiate the fish when it comes ashore.

Others may use a simple conveyor belt past either a gamma ray or machine source.

The French have designs for a small scale field irradiator for potatoes.

RADIOACTIVE FOOD?

The first concern of most people is whether or not food becomes radioactive. Ionising radiation with high energy can cause radioactivity to be created in the material that is bombarded. (15)

> The energy level is usually expressed in 'electron volts' (eV). Above about 10 to 15 million electron volts (MeV) it is possible for significant amounts of radioactivity to be created.

It is therefore important that only lower energy ionising radiations are used in irradiation of food.

Even so it is still possible for some trace metal compounds in the food to be made radioactive. Below the 10 MeV level however, the amount of this induced radio-activity is small and decays very rapidly. If foods are stored before use the level of radiation is likely to be insignificant and well within the range of natural radioactivity found in food anyway. (1)

The other way food could become contaminated with radioactivity is if the radioactive source were damaged. Obviously great care will be taken to prevent this kind of accident. (16)

Thus, provided irradiation is properly controlled, food should <u>not</u> become radioactive.

RADIOACTIVE SOURCES FOR FOOD IRRADIATION

It has been suggested that the nuclear wastes from power stations could be used as a radioactive source for food irradiation. (16) This is not feasible because these wastes contain a wide range of radioactive materials some emitting radiation with energy above the critical level. (1)

Two radioactive materials have been identified which are suitable and have energies considered low enough to be safe for use in food irradiation Cobalt 60, and Caesium 137.

> Cobalt 60 gives off two gamma rays of 1.17 and 1.33 MeV and Caesium 137 which gives off 0.66 MeV gamma radiation. A mixture of Caesium 137 and Caesium 134 can also be used. Radiation from these radioactive istopes is well below the 10MeV threshold and after storage there should be no measurable levels of induced radioactivity.

Disposal of radioactive cobalt and caesium currently presents a considerable problem because of quantities produced in nuclear wastes from power stations and the length of time they take to decay. The nuclear energy and weapons industries are therefore keen to find commercial uses for them. On the other hand it has to be admitted that the viability of using these sources depends on the continuing existence of the nuclear power programme. (16)

The other possible sources for irradiation include beams of electrons, and x rays which are created when a metal target is bombarded with electrons. These 'machine' sources give off a wide spectrum of energies and greater care must be taken to ensure that the maximum energy is below the 10 MeV threshold. Electrons do not penetrate materials as far as gamma or x rays and so are only useful for irradiating the surface of foodstuffs. (1)

RADIATION DOSES

Dose is commonly used to mean one of two distinct things. It is either the amount of radiation received or, in the case of exposure to people, it is related to the amount of biological damage done. In measuring the dose to food we are concerned about the amount of energy that has been deposited as a result of irradiation. The old unit for dose was the Rad; this now being replaced by the Gray (Gy). Very large doses up to one million Rads are being considered for food irradiation. Therefore the doses are more often given in Mega rads (Mrads) or Kilo Gray (kGy).

a million Rad (1 MRad) = 10 kGy (10,000 Gray)

To give some idea of the scale of these doses, a chest x ray will deliver about 10 milliRad (0.01 Rad) and an average dose from natural background radiation will give about 100 milliRad (0.1 Rad) per year. The food irradiation dose is therefore 10 to 100 Million times these common doses.

The changes produced in the food increase as the dose goes up. This applies to both the desired and the undesirable changes. (1)(2)

USES OF FOOD IRRADIATION

As explained above, radiation produces chemical changes in the food and these in turn have biological effects. In some cases the exact mechanisms are still not fully understood.

The following effects can be produced

RADURIZATION - low doses, usually below 1 kGy (0.1 M Rad) 100 or RADS

* sprouting of vegetables such as potatoes and onions can be inhibited so that they keep longer

* Ripening of fruits can be delayed so that they keep longer and can be transported longer distances

* Insect pests in grains such as wheat and rice, or in spices and some fruits can be killed. This might replace current methods involving gas storage or fumigation treatments that are hazardous to workers, and could reduce losses of foodstuffs.

uncritical + misleading presentation

RADICIDATION -medium doses, between 1kGy and 10kGy (1.0-M Rad) 100,000 - 1,000,000 RADS

* The number of micro-organisms that lead to food spoiling such as yeasts, moulds and bacteria could be reduced and so extend the life of foods or reduce the risk of food poisoning. This might be important in the case of salmonella in chicken or fish.

the claim to reduce the risk of food poisoning will come with increased risk from altered nutrients

RADAPPERTIZATION - High doses above 10 kCy (1 M Rad)

1,000,000 plus

* At these extremely large doses, higher in fact than the 10 kilo Gray (1 Mega Rad) doses being proposed at present, food can be completely sterilised by killing all bacteria and viruses. This would be used mainly for meat products allowing them to be kept indefinitely. (1)

and spices + herbs; what about percentage of lipids, loss by rad. K, URR production? what other nutritional value?

These effects can be said to extend the 'shelf life' of foods. In these cases irradiation is used as a preservative.

IMPROVEMENT OF FOOD BY IRRADIATION

In addition to the food preservation benefits claimed for irradiation a number of other "improvments" in quality have been claimed. (36)

Improvement of baking and cooking quality of wheat including the..ability to add up to 15% soya flour to wheat flour without loss of baking quality. Irradiation also "improves" the elasticity and volume of dough in bread making. A number of additives are currently used to increase the bulk, and the water and air content of the standard white loaf. Yeast can be stimulated by irradiation leading to faster bread making. (2) While this has obvious benefits to the large baking firms it is a matter of opinion whether this leads to an improvement in bread quality. (37)(77)

of what nutritional value is this "wheat" for white bread why is it better to make bread faster? Are there the only jobs + not enough workers what about the temp montagnac effect on sugar & grain rad

Irradiated barley can increase yield during malting by 7% - a fact of interest to the brewing industry. Irradiation can be used to 'age' spirits (38) and irradiated grapes yield more juice when processed - possibly benefiting the fruit juice and wine making and distillery industries. Irradiated sugar solutions can be used as anti-oxidants, possibly replacing other chemicals used for this purpose in processed and prepared foods.

The time needed to reconstitute and cook dehydrated vegetables, peas and green beans is reduced if these are irradiated. Since cooking times for dehydrated foods are already very short it is debatable whether this is any real benefit.

It is claimed that irradiation enhances the flavour of carrots and suggested that it could be used for 'tenderising' of meat. (1)

Food that has been contaminated or spoiled can be sterilised by irradiation and so made safe for human consumption. The joint expert committee of the WHO/FAO/IAEA are explicit that irradiation should not be used to make an unsuitable product suitable for consumption, and that food should always be wholesome before irradiation. There are however, pressures arguing that this should be considered. (17)

Most of the basic mechanisms of these "favourable" changes in food quality are not fully understood. (1) (2) (12)

On balance most of the above uses are not necessities. They are either luxuries or techniques which might benefit the manufacturer with no clear benefit for the consumer.

What you want to say clearly is that the consumption of these foods is unnecessary due to changes in the food.

Other non food, but food related uses, include modification of starches for the paper and textile industries and radurization of gelatin for use in the photofilm industry.

3 - IS FOOD IRRADIATION SAFE?

In this section we examine the evidence for and against the claims that irradiated food is completely safe. (19) (75) (76)

FOOD HYGIENE AND PUBLIC HEALTH

The effects of irradiation on food described above are regarded as desirable from the point of view that they increase the storage time or "shelf life" of foods. Irradiation should not however be regarded as a panacea for all food preservation problems. Along with the desired effects a number of highly undesirable ones are also produced. Reducing some (but not all) of these may be possible through use of heat or of very low temperatures, removal of oxygen during irradiation, or use of some chemical additives. In these cases irradiation becomes only a part of the preservation process.

In many cases refrigeration will still be needed throughout the storage life of the product and irradiation will not replace this as one of the main methods of preservation.

For long term storage sealed packaging may often be needed as recontamination can occur at any time. Food irradiation should not be seen as a technical solution to all food hygiene problems. (1)

WHOLESOMENESS OF IRRADIATED FOOD

In the English language, wholesomeness is a word that combines the ideas of nourishing and healthful. There is no similar word in other languages. This is unfortunate. In the international forums, such as those of the United Nations expert committees, the word has been debased so that it now only covers the concept of safety and safety only narrowly defined as the absence of

a) harmful toxic chemicals
b) harmful microbiological effects
c) significant impacts on nutrition
d) induced radioactivity in the food

Most people will find it reassuring to know that, provided irradiation is properly controlled, the food is not made radioactive.

On the other safety aspects the situation is less clear cut. It is possible to argue that the risks are slight, and likely to be acceptable if the whole process is properly controlled. What is not acceptable however is the use of the term "wholesome" for foods that are to be sold as fresh but, in fact may have been significantly denatured in the process of irradiation. There is a big difference between safe for human consumption and wholesome. This is a distinction the public

perhaps, the question we must all ask our "leaders" is, "Are you willing to feed your own country's Olympic hopefuls on a diet of strictly or even partly irradiated foods?" How about children, pregnant women, etc. ...?

can and do make and which they need to be allowed to continue to make as a fundamental right.

If consumers are not to be misled we should insist on clear and unambiguous labelling of all irradiated food products.

VITAMINS

Irradiation does severe damage to most vitamins, particularly vitamins A,C,D,E & K and some of the B vitamins; B1 in particular, but also B2, B3, B6, B12 and folic acid are affected to some extent.

TABLE 2 : SOME REPORTED PERCENTAGE VITAMIN LOSSES. (Source: Refs 1, 2 & 12)

Food	Vitamin A	B1	B2	B3	B6	B12	C	E
Milk	60 - 70	35 - 85	24 - 74	33	15 - 21	31 - 33		40 - 60
Butter	51 - 78							
Cheese	32 - 47							
Grains and Flour								
Wheat		20 - 63	-	15	3	-	-	-
Oats		35 - 86						7 - 45
Rice		22						
Beans	-	-	48	-	48	-	-	-
Meats								
Beef	43 - 76*	42*- 84*	8 - 17*	-	21*- 25*	-	-	-
Pork and Ham	18*	96*	2*	15*	10 - 45*			
Chicken	53 - 95*	46 - 93*	35*- 38*		32*-37*			
Eggs	-	24 - 61*	-	18	-	-	-	17
Fish								
Cod	-	47	2*	-	-	-	-	-
Haddock		70*- 90*	4*					
Mackerel		15 - 85*			26			
Shrimp	2 - 27	70*- 90*						
Potatoes	-	-	-	-	-	-	28 - 56	-
Fruits								
Fruit Juices	-	-	-	-	-	-	20 - 70	-
Nuts	-	-	-	-	-	-	-	19 - 32

Note : some vitamins are relatively undamaged by radiation but absence of a figure in the table above does not imply that a food has been cleared. In general more work needs to be done on a comprehensive study of vitamin losses.

* All % losses are at doses below the 10kGy proposed clearance level unless *. In these cases doses are below 60 kGy being suggested for sterilisation of meat products

The extent of the loss depends on the vitamin and on the type of food and the dose given. Fruit juices will suffer more than fresh fruits and these more than vegetables, grains and meat products. Generally speaking the more complex the food the less it suffers vitamin losses during irradiation.

In an attempt to justify the claim that these losses are not nutritionally significant it is said they are

a) no more serious than occur during normal storage
b) no more serious than occur in cooking and heating.

The first statement is untrue and the second is misleading. Vitamin B1, for example, is not only very sensitive to radiation damage but the further losses during storage are greater than expected during normal storage of unirradiated foods. (12) Vitamin E is not only virtually destroyed in some irradiation processes, but is destroyed even if it is added as a supplement after irradiation. (1)

As far as cooking is concerned, it is true that vitamin losses, particularly of vitamin C, do occur, but it is the grains, meats and some vegetables that are usually cooked whereas we obtain a large portion of our vitamin C from fresh fruits and uncooked vegetables. The loss of vitamin B1 during cooking is again greater when the food has been irradiated. (1)

It may well be true that a family with a normal healthy diet in a developed country like Britian will not suffer from major nutritional deficiencies as a result of irradiated food. We do however need to be concerned about those whose diet is already deficient both at home and abroad. This is far more widespread than usually appreciated. Poor eating habits are often forced upon people by poverty, or by the pattern of family working that leaves them overdependent on processed "convenience" foods.

There has so far been no detailed study of the impact that irradiation of a significant portion of our food would have on people on low income diets. Without this study the full impact of irradiated food on diet cannot be said to be satisfactory.

Since irradiated food with significant vitamin losses may still look fresh it is extremely important that it is clearly labelled so that the consumer is not misled.

FOOD QUALITY

The appearance, feel, texture, taste and smell of food are the most immediate perceptions of food quality. Irradiation may inhibit the ripening of fruit. It also produces a softening of the tissues and leaves many fruits more susceptible to bruising.

Of 27 fruits investigated, the process has been found beneficial for only 8.

TABLE 3 - RESPONSE OF 27 FRUITS TO IRRADIATION

BENEFICIAL EFFECTS (delay in ripening (a) delay in ageing (b) or control of storage decay (c)			
BANANAS	(a)		
MANGOES			
PAPAYAS	(a & b)		
SWEET CHERRIES	(b)		
APRICOTS			
TOMATOES	(c)		
STRAWBERRIES			
FIGS			
NOT BENEFICIAL (damaged by radiation (d) accelerated ripening (e) or no positive benefit (f)			
PEARS	(d)	PEACHES	(e)
AVOCADOS		NECTARINES	
LEMONS			
GRAPEFRUIT		PINEAPPLES	(f)
ORAGNES		LYCHEES	
TANGERINES		HONEYDEW MELON	
CUCUMBERS			
SUMMERSQUASH			
BELL PEPPERS			
OLIVES			
PLUMS			
APPLES			
TABLE GRAPES			
CANTELOUPES			

(Source Ref 1)

In general fruit suffers more from irradiation than the fungi it is used to kill.

Potatoes may be slower to sprout if irradiated. Once irradiated, the bruising and cuts that occur in harvesting are also slower to heal. For this reason a delay after harvesting is recommended before irradiation. At the same time, irradiation also increases the susceptibility to subsequent fungus attack and rotting. Careful inspection and sorting must remove soil and any potatos that are rotten or damaged. Otherwise the whole batch will quickly spoil. It may be that these factors, brought on by particularly adverse damp harvesting conditions, were reasons for the financial failure of the Canadian Potato Irradiation project in the mid 1960's. (69)

Onions on the other hand are best irradiated within 4 weeks of harvesting. Damaged or rotting onions also easily spoil the whole batch. Both onions and garlic show signs of internal browning after irradiation (2), a factor that reduces their commercial value.

Milk and milk products do not irradiate well. Phrases such as "chalky", "scorched", "candle like" or "burnt wool" have been used to describe the flavour and smell of irradiated milk (1).

Fats equally suffer from irradiation. "Musty", "nutty" or "oily" have been used to describe the effects. Oils suffer even more. This is of particular importance in attempts to treat oily fish, mackerel for example. (1)

Meat, one of the main foods for which high dose treatments are being developed, develops what has been characterised as a "wet dog" smell. (1)(18)

The exact nature of what has been called these "typical irradiation flavours" and odours has not yet been fully characterised. Perhaps even more significantly the major culprits in terms of the foods' chemistry have not been fully identified - so little is fully understood about the masssive and random rearrangement of the and molecular structure of the proteins, fats, carbohydrates, enzymes and residual chemicals in these foodstuffs.

IRRADIATION AND ADDITIVES

One of the major selling points in favour of food irradiation has been the claim that it will reduce the need for harmful chemical additives in food. (19)(20)(21)(22)(23)(24)

There is a very real and well founded public concern about the extent to which foods are being adulterated with chemicals. Processed foods rely on additives not merely for preservative effects but for flavours, colours, and bulk fillers too.

In addition there is reason to be concerned about pesticide residues in food and the harmful effects these are having on agricultural and other workers. THE LONDON FOOD COMMISSION is producing reports on the health hazards of pesticide residues (26), and of food additives for both consumers and workers. (25)

to look forward to ...

It is particularly worrying then to find that, far from eliminating additive use, the process of irradiation will itself require use of a number of additives in order to control some of the undesirable effects of irradiation. (1). Table 4 below lists some of the additives that are claimed to be eliminated or reduced by irradiation and those proposed for use with irradiation.

Table 4 - IRRADIATION AND ADDITIVES

Some hazardous Additives which (it is claimed) irradiation might replace.			Some Additives which might be needed to reduce undesirable effects of radiation.		
*E251	Sodium Nitrite	m,c,	*E251	Sodium Nitrite	m,c,
*E230	Diphenyl	c,	*E230	Diphenyl	c,
E220	Sulphur Dioxide	c,	E221	Sodium Sulphite	i,
E210	Benzoic Acid	m,i,	E300	Ascorbic Acid	i,m,
	Propylene Glycol	c,	E321	(B.H.T.)	c,
925	Chlorine	i,	E320	B.H.A.	c,
926	Chlorine Dioxide	i,	371	Nicotinic Acide	i,e,
E281	Sodium Propionate	m,	924	Potassium Bromate	i,
E236	Formic Acid	i, (banned in U.K.)		Sodium tripoly-phosphate (TPP)	i,
	Ethylene Oxide	c,i,m,t,		Sodium chloride (salt)	
	Methyl Bromide	i,		Glutathione (for Vit. B1)	
	Ethylene Dibromide	i,c,		Niacin (for Vit B6)	
	Propylene Oxide	i,		Sodium Ascorbate (for Vitamin C)	
	Hydrogen Peroxide	i ,			

Key:-

i = irritant, c = carcinogen - (known or suspected cancer causing agent in animals and/or humans) m = mutagen (capable of causing mutations) t = teratogen (capable of causing damage to developing fetus) a = capable of causing allergic reactions

Source (Reference 1) Hazards information refs (25) and (71).

The use of such additives is not to be restricted to the high dose applications where the obnoxious radiation flavours become pronounced but are also proposed for low dose uses to prevent discolouration and other undesirable effects such as bleeding and breakdown of fats in meat. To control these the following steps for preservation treatment of meat are proposed:

1. cut into portions
2. dip in a dilute solution of sodium tripoly-phosphate* (or other condensed phosphate)
3. film wrap
4. vacuum pack film wrapped portions in a bulk container
5. refrigerate at 0 to 5 degrees Centigrade
6. irradiate with a dose of 1-2 KGy
7. Ship and store at 0-5° C
8. Remove from container for display (no more than 1/2 hour before display)
9. refrigerated display 0-5 degrees
10. sell within 3 days

In this way it is proposed to extend the 'shelf life' of retail cuts of meat to 21 days. (1)

* Sodium tripolyphosphate is a chemical used for cleaning grime off walls (it cuts grease). It is also irritating to the skin and is used as a purgative as well as its use here in food preservation. (27)

Approval of irradiation, if it is given, should be linked to

bans and other restrictions on the use of chemical additives that are currently used as preservatives. Unless this is done we will be adding to the range of hazards not, as those in favour of irradiation claim, reducing the current adulteration of foods.

TOXIC CHEMICALS

Chemicals created in the irradiated food are called "radiolytic products" or "radiolytes". Many of these are similar to chemical changes that occur in other forms of food processing such as cooking. Some however are unique to irradiation. (1) (2) (12)

the connection to cooking is misleading; g-rad is not a cooking tech and cooking will simply add to the radiolytes prod by g-rad.

Because of the complexity of the reactions, it is difficult to identify all of these radiolytic products and to test them in the usually accepted way that chemical additives for example would be tested. Initially irradiated foods were fed to animals. While overall, the results have been reassuring, testing of a potential hazard usually involves feeding large quantities of the chemical. Testing by just feeding the food is inadequate. Only small quantities of the unique radiolytes exist in the food. Testing can therefore miss underlying problems or long term hazards.

More recently a number of radiolytic products have been isolated and more normal high dose testing has been done on these.(1) Again the results have been claimed as reassuring. Even though some adverse effects have been found in experimental conditions it is claimed that these are not likely to occur with irradiated foods under practical conditions, i.e. provided these conform to the international Codex Alimentarius standards and the guidelines developed by the Joint Expert committee of the WHO/FAO/IAEA. (1)

It needs to be noted that the WHO/FAO/IAEA committee initially required testing on all iradiated food products. In 1976 this requirement was removed. Results from one food could be applied to another provided that the doses were below a limit of 10 kGy. The US Food and Drug Administration however insists that food irradiated in the medium dose range could contain enough unique radiolytes to warrant toxicological study. All foods irradiated above 1 kGy in the US are required to be tested. (28)

Clearly the dose is a critical factor. The higher the dose the more radiolytic chemicals are created and the greater the potential risk. Initially the WHO/FAO/IAEA specified both maximum and minimum doses that should be used in giving clearance to particular foods. (4) The minimum dose guaranteed that the food would have the changes expected of it and the maximum guaranteed that undesired effects would be limited. In 1980 this requirement was changed and only an average dose was specified. The Committee accepted in doing so that doses up to 50% greater than this average could

is this the "method" by which the Expert Comm. is said to have arrived at a 1,000,000 RAD dose - Ple

result. (5) In some quarters this has been interpreted as giving clearance før maximum doses to be 15 kGy. (2)

Thus, though testing has been undertaken over a number of years and the dose ranges within which irradiated food can be regarded as safe have been defined, there has been a steady relaxing of the requirements for testing, and for control of doses. These changes appear to have more to do with commercial considerations than public health.

The public need far more information than simply being told that irradiated food is "safe." The public needs to know about the scientific uncertainty that underlies these statements from the expert bodies and to be given details of some of the adverse effects that have been found.

In chemicals that can cause cancer or genetic defects it is safest to assume that there is no safe level of exposure to such chemicals. Just as with radiation, any dose can cause the initial damage that develops into a cancer. Damage to the genetic blueprint may cause miscarriage or defects in future generations. The fact that a chemical change is small and can be decreased considerably by suitable techniques, does not eliminate the risk: it merely reduces it. (16)

Evidence of cause for concern

Lethal effects from feeding irradiated food to mice have been observed. Other studies have not confirmed these effects.(1) The problems surrounding safety in this area ar compounded by lack of credibility in some research. In 1968 the US FDA rejected the US Army's research on irradiated pork, and withdrew clearance from irradiated bacon given in 1963. In the 1970's the US Army contracted their research to Industrial Bio Test Ltd. In 1983 the company's officials were convicted of performing fraudulent safety research for industry and government. (29)

Some animals fed irradiated food have been found to have reduced growth, changes in white blood cells and kidney damage. The chemical agents responsible have not been identified but some of the changes may be due to effects on the body's immune system. There is also a suggestion that vitamin reduction in irradiated foods is a cause of some of these health effects. (2)

A similar conflict of evidence exists over whether irradiated food can cause genetic mutations. The balance is in favour of the view that they do not, but some uncertianty remains. (2)

Polyploidy- a chromosome defect - has been observed inchildren, monkeys and rats fed irradiated wheat, and hamsters fed irradiated diet. Other studies of feeding irradiated wheat or foods irradiated for human consumption to rats have not found polyploidy. It appears that the damage that leads to such

chromosome defects decreases when the food is stored and this together with the variety of components of food may account for the differences observed. Even so this is reinforces the need for vigilance and for setting strict conditions on the process and subsequent storage times for irradiated food products. (30)

The most recent US scientific research raises questions about safety of irradiated chicken. The Report published in 1984, concludes:

> "two of the studies ... had some possible adverse findings which will require careful consideration before the process can be declared safe". (32)

Comparison with other processes

These uncertainties about safety do not appear in the reports of the WHO/FAO/IAEA or British 'experts' on irradiation. The conclusions are always expressed in terms of the benefits of food irradiation and the safety of irradiated foods. If chemical changes are referred to at all they are said to be "not significant" or similar to those produced in other processing techniques.

Some radiolytic products are similar to those produced by other processing techniques. The quantities produced however can be very different. Hydrogen Peroxide for example, continues to develop after irradiation. Stored foods can have 2-3 times the levels found in unirradiated foods. (1)

Chemical additives are likely to be needed for use with irradiation. Products created by interaction between these chemicals and radiolytic products need to be tested also. As noted above, some of these additives may present toxic hazards in their own right in any case. (25)

Other common radiolytic products, can be removed after irradiation. This can conflict with the need for sealed packaging to prevent recontamination. Such attempts at removal

> "may correct some undesirable consequences of high dose irradiation but leaves other consequences uncorrected and thus the method is of little practical value" (1).

Concern has also recently been expressed about contamination of foods by some plastic film wrappings. (31) Again it is reasonable to request that studies be done on the changes that occur with irradiation and the combination products of these chemicals with radiolytes when the food is irradiated.

One argument frequently used to dismiss concerns about possible toxic chemcial hazards is that irradiation produces effects similar to those found in cooking. In the case of the

unique radiolytic products this is clearly untrue. While in general some of the chemical interactions are similar there have in fact been very few studies that directly compare the effects of irradiation and cooking. (1)

It is worth noting that in the case of irradiated meats where doses of 20 to 60 kGy are proposed for sterilisation, a dose of 30 kGy was found to produce some changes that were equivalent to heating meat at 170 degrees C for 24 hours. This is hardly an example of cooking that most people would use for comparison. (1)

Summary

Testing of chemical products of irradiation in food indicates that **some possibly harmful effects can occur.** The way these are dismissed is disturbing. They are frequently called "insignificant" or "not likely to occur in practice". The changes to the rules for testing the hazards, and for limiting the maximum and minimum doses to the food is also disturbing. It suggests that there are very strong pressures from interests that want to believe food irradiation is safe and who are more concerned to convince the public than objectively report the problems and uncertainties.

There are a large number of potentially harmful additives that are still approved for use in food in Britain. Any testing system that is less stringent than the one that has allowed these additives to slip through the safety net hardly inspires confidence. For this reason we have stressed that testing of irradiated foods, and the chemical products of irradiation in food, needs to be as strict or stricter than required for additives.

The public have a right to be given unbiased information on the possible harmful effects and not bland assurances that hide uncomfortable evidence under value judgements. It is the job of the public and the political processes to decide whether these effects are significant, and to lay down the regulations under which the risks might be considered acceptable. When science and scientific experts enter this area to pre-empt discusssion of these issues we have reason to be concerned.

MICROBIOLOGICAL HAZARDS

There is a possibility of irradiation causing mutations in viruses, insects and bacteria in food leading to more resistant strains. (16) There are numerous examples of insects developing resistance to pesticides for example. So far studies have not shown this to be a major problem with irradiation though some uncertainty remains. Some strains of resistant salmonella have been developed by repeated irradiation under laboratory conditions. Radiation resistant bacteria have been found in environments with high natural or

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man made radiation levels (2) and development of such resistance might be a problem around large scale irradiation plants. (1)

Increased production of aflatoxins following irradiation was first found in 1973 (33) and confirmed in 1976 and 1978.

Aflatoxins are powerful agents for causing liver cancer. The production of aflatoxins was found to be stimulated by irradiation at doses approved by the WHO/IAEA/FAO expert committee.

Table 5: Stimulation of Aflatoxin Production

Food	% increase	
wheat	increases with dose	
corn	31%	
sorgum	81%	
millet	66%	
potatoes	74%	
onions	84%	(34)

Aflatoxins occur in damp environments on fungus spores on grains or vegetables. Control of humidity in storage becomes even more important in the case of irradiated than non-irradiated foods.

Not all the micro-organisms on food are harmful. Some perform useful functions particularly in warning us food is going off by giving off a putrid smell. Yeasts and moulds also compete with harmful bacteria and so provide natural controls on growth of these bacteria.

One example of the possible effects of irradiation arises in considering the use of irradiation to reduce the risk from salmonella in chicken or fish.

Irradiation of chicken could kill not only the salmonella bacteria but also the yeasts and moulds that are the natural competitors of botulinum, the bacterium that causes botulism food poisoning. It will also kill the organisms that cause the putrid odour. Yet, at the doses proposed, the botulinum will not be killed. Under the right conditions the botulinum could multiply and become a health hazard without the consumer having any warning smell. (1) (35) (16)

With fish this is less likely. At the doses proposed there are likely to be enough spoilage organisms left to multiply under similar conditions to the botulinum so that the food smells unacceptable when botulism becomes a hazard. (1)

Clearly such possibilities reinforce the need for strict control of both the irradiation process and the conditions under which irradiated food is stored and handled.

4) WORKING WITH RADIATION

Exposure of food to radiation might, in the end, have some beneficial effects. Exposure of workers has none.

Large doses of radiation can kill by destroying cells in the body so that various organs cease to function, or by damaging the body's immune system leaving it susceptible to disease. Some acute effects such as skin burn, nausea, diahorroea are also experienced which may not cause death. Years later exposed people may suffer from cancer, or their children from genetic damage as a result of the exposure. Even below doses where any immediate effects are experienced there remains an increased risk of cancer, gentic damage, or susceptibility to disease. (1)(11) (13)(14)

There is no threshold or safe level below which these long term effects do not occur.

When radiation strikes a living cell one of three things can occur

* any damage done is adequately repaired
* the cell is killed. In this case, provided too many cells are not killed at once the body will eliminate the dead cells and little harm will be done
* the cell will be damaged but survive to reproduce in this damaged form. Years later, successive reproductions from the damaged cell may show up as what we call a cancer, or be passed on as a genetic defect to future generations. (13)(39)

There is also a growing body of evidence that radiation causes a more general reduction in health by weakening the body's resistance to disease. (14)(40)

The crucial point is that there is no dose below which these effects do not occur. It is like walking across a main road blindfold. Do this in the rush hour and you'll be killed. Do it at midnight when there is less traffic and you can be more lucky but if you do get hit by one of the few vehicles around you can be just as dead. A little bit of radiation doesn't give you a little bit of cancer. Any dose however small, can be the one that does the damage. (13)

The extremely large doses involved in the irradiation of food could result in exposure to workers in the industry. They face considerable risks in the event of malfunctioning equipment, leaking radioactive sources, or accidental exposure to the source. In addition the irradiation chamber will be a very corrosive atmosphere requiring "regular and preventative maintenance". (1) Irradiation sources will also need to be produced, transported stored and installed and the spent

sources replaced. This whole process cannot be divorced from the wider processes of the nuclear power programme without which it could not exist. At every stage workers can be, and usually are, exposed to "low levels" of radiation. (74)

As a general principle any exposure to radiation should be avoided unless it can be justified in terms of some overall benefit. Even then the exposure should be kept as low as possible (1)(41)

In addition there are regulations setting limits on the maximum dose that workers and/or the public can be exposed to. Unfortunately these were set before the principle that there is no safe level, was established. As a result some radiation using technologies, particularly uranium mining, nuclear fuel handling and plutonium reprocessing, developed under standards that can now be seen as inadequate. It is however very costly both in economic terms, and more importantly in terms of the safety image of these industries to admit the error. Considerable effort, that could be better spent on radiation protection for workers and the public, has gone into attempting to maintain the myth that exposures within the limits are "acceptable".

ACCEPTABLE RISK?

A person is permitted to receive a maximum of 5 rem per year total exposure to radiation at work, or a maximum of 0.5 rem as a member of the public. A rem is a measure of the biological damage done by radiation. For Gamma radiation, electron beams and x rays, it is effectively the same as the RAD used to measure doses to food.

> A new unit the SIEVERT is replacing the rem. Since the Sievert is a large dose compared to the likely worker doses, the milli-sievert (mSv) is commonly used (0.001 sievert). 1 rem equals 10 millisieverts (mSv).

Since the 5 rem (50 mSv) limit was set in 1957 it has become clear that exposure to this level of radiation represents a completely unacceptable level of risk.

> A worker receiving this dose each year would run a risk 8 to 18 times higher than is acceptable for a "safe" industry. (42)(43)(44). A "safe industry" accepts that 1 worker in 10,000 will die each year: or, over a lifetime, 1 in 200 workers will die from an accident at work.
>
> Clearly a risk 10 or more times greater than this is completely unacceptable.

For a worker to face radiation risks equal to risks in a "safe industry," the exposure limit will need to be reduced to around 0.5 rem (5 mSv) a year. Even then radiation workers will face all the normal risks of other accidents and so still be doubling their risk of dying from the job. (45)

On top of this, these risks apply only to fatal cancers and serious genetic damage over 2 generations. The non fatal but debilitating effects of other cancers, the less serious or long term genetic effects, and the general lowering of the quality of health from radiation should not be forgotten.

The need for a drastic reduction of by at least a factor of 10, in the dose limits is reinforced by the more recent scientific evidence on the risks of radiation exposure.

> The national standards and the risk estimates are usually based on the recommendations of the International Commission on Radiological Protection (ICRP) - a self appointed body of experts closely identified with the nuclear industry. (46) (13) Two recent international reviews of the scientific literature have put the risks between 2 and 10 times higher than ICRP. (47)(48) Further evidence suggests that the risks may be higher still. (49) (50)(51)(52)(53)

The most recent evidence from a study of UK Atomic Energy Authority workers indicates that the risk is 4-7 times, and could be 15 times greater than estimates by the ICRP. (53)

NEW REGULATIONS?

In these circumstances it might have been expected that the UK Health and Safety Executive's new Ionising Radiation Regulations due in force in 1986 would have revised and improved standards for radiation protection. Unfortunately the reverse is the case. In some significant ways these new regulations relax the already inadequate standards currently in force. (54)

Under the new ICRP based system for calculating worker doses from exposure to different parts of the body, the permitted dose to a number of organs is allowed to rise by 2 to 8 times the current limits.

Table 5 - Current and Proposed Limits for organ exposures

ORGAN	CURRENT LIMIT	PROPOSAL LIMIT	FACTOR INCREASE
Thyroid	30 rem.	50 rem.	1.7 x
Breast	15 rem.	32 rem.	2.1 x
Bone	30 rem.	50 rem.	1.7 x
Red Marrow	5 rem.	42 rem.	8.4 x
Lung	15 rem.	42 rem.	2.8 x
Gonads	5 rem.	20 rem.	4.0 x
Skin	30 rem.	50 rem.	1.7 x
Extremities	75 rem.	50 rem.	0.67 x
Head (In some circumstances)			3.0 x

(45)

Most of the limits on amounts of particular radioactive materials that a worker can absorb are relaxed; in some cases quite dramatically. (43) The new regulations do suggest that exposures over 1.5 rem (15 mSv) should be investigated, but at the same time the new regulations only require monitoring of workers in areas where they are likely to receive doses greater than this 1.5 rem investigation level anyway.

These relaxations are taking place despite the private view of many within the nuclear establishment that exposures need to be below 1 rem (10 mSv) to be considered acceptable. (56)

DESIGN LIMITS FOR FOOD IRRADIATION PLANT

Clearly in these circumstances food irradiation technology will be introduced into a regulatory framework that does not provide adequate protection for radiation workers. Once established the technology will be yet one more reason why improvements cannot be made in the future. It will undoubtedly then be argued that changes will cost money and jobs.

A number of eminent scientists in the field of radiation

research and radiological protection have argued for a new **Design limit** for radiation technology - a bench mark at 0.5 rem (5 mSv) which should be the maximum a worker is likely to receive from all normal operations involving exposure to radiation. (57)(58) Unions in the UK and Canada have also called for such a design limit and for a phased reduction of all radiation exposures to below this limit. (55)(59)

For most purposes a 5 mSv limit is already feasible. (42) (74) In the case of a new technology such as food irradiation it could be guaranteed as plant would be designed to ensure that it was not exceeded.

This will not, as indicated above, remove all risks but would begin to bring these risks into line with those faced in other industries. Just like consumers, workers need to be allowed to make informed choices about the risks and to have adequate protection laid down by a framework of regulations.

5) ECONOMICS OF FOOD IRRADIATION

Food irradiation is likely to be a very costly process and depend on a variety of factors including

- capital costs of irradiation plant
- cost for radiation sources
- types and quantities of foods to be irradiated
- transport costs
- the market image of irradiated foods
- competition from other processes

The 1981 report of the WHO/FAO/IAEA called for investigation of the economic prospects for food irradiation. (5)

There are some people who will ague that the market place will sort out all these problems. If the price is right the consumer will buy irradiated foods. If not then irradiation won't happen. Reality is more complex than this simple grocer shop view of economics.

A full study of the economics of food irradiation should consider the impact the technology would have on the whole food industry, on employment within the industry, and on patterns of marketing and consumption. Just as hidden subsidies can make a process appear financially beneficial, many hidden social costs could indicate that it is after all undesirable. Such a study would help in assessing claims made about the economic benefits of food irradiation.

COSTS OF IRRADIATION PLANT

There are currently around 70 pilot or experimental plants operating or under construction worldwide. These vary from portable field units and plants mounted in ships, through to large scale multi-purpose irradiation plants. There are, in addition, a number of medical facilities dealing in sterilisation of medical products attached hospitals.

In Britain there are 10 facilities that currently irradiate medical supplies or animal feed. Of these only four, all owned by ISOTRON Ltd will be be able to handle commercial food irradiation. One other might be able to do so. Some hospital facilities might be used as part of hospital catering.

Obviously the costs of building such plants vary widely. A large scale production facility based on a U.S. design was costed at £1.25 million in 1984. (64) A recently completed facility for ISOTRON Ltd in Britain cost £3.0 million. (61)

The major running cost in an irradiation plant is the radioactive source. The amount of radioactive source material will depend on the type of food (and hence the dose required) and the amount to be processed. At current market prices a 1 megaCurie Source of cobalt needed for a large facility would cost around £100,000 per year. (64).

With costs on this scale and with a virtual monopoly on the current UK facilities, it is only natural to find considerable pressure from ISOTRON for removal of the current ban in the U.K. Frank Ley, the Director of ISOTRON was a consulting advisor to the government's advisory committee on irradiated foods. Sir Arnold Burgen, the chairman of the committe, is a part time director of Amersham International, Britain's leading isotope manufacturer. (9) (23)

The major source of radioactive cobalt 60 has been Canada where the CANDU reactor is well suited to producing the isotope. Cobalt 60 may soon be produced in large quantities in Britain as radioactive wastes if permission to build the U.S. style Pressurised Water reactor is granted. In the meantime the alternative isotope, Caesium 137 exists in large quantities as waste from the Sellafield (formerly Windscale) reprocessing plant in Cumbria. (65) (66)

Food irradiation plant running costs might come down significantly if cheap radioactive cobalt or Caesium sources are provided as a way of dealing with these problematic nuclear wastes. Even so, the initial costs are high and there will be considerable pressure to utilise the facilities to the full.

The problem with large scale irradiators is that food needs to be transported from the field or the manufacturer's plant and the irradiated food again transported to storage facilities or markets.

Smaller "Field" irradiators for fruit and vegetables, and fish, irradiators on board ships have been developed. Some technical problems such as potato damage in harvesting may limit their usefulness. Maintaining health and safety standards can be a much greater problem in field uses of radioactive materials.

WHO WILL BENEFIT?

In Britain the major immediate beneficiary of a decision to permit food irradiation will be ISOTRON the one company that has all the major irradiation plant. It is not therefore surprising to find its director among the leading advocates of the process. In the longer term it is unclear whether the large food manufacturers and/or the large retailers will invest in the process. The margins for profit on food are small. Profits depend on large turnover, or from being able to command a higher price for a food product. Currently this

is done by processing foods and charging the consumer for this processing on the basis of its "convenience" value. Alternatively it is done by presenting the food item as a quality product:- "fresh," "the best of the crop," "the best cut," and more recently, "natural" and/or "unadulterated." The underlying idea being the association of the quality image with wholesome and healthy food. It is clear that irradiated foods will be marketed using both the convenience and quality images.

Extended storage ability will be one selling point. Fruits and vegetables and meats and fish will keep longer in the home. How real this will be given the extent to which refrigeration/freezer technology is already available is in some doubt. The advantage might lie in the use of irradiated and airtight sealed packaged foods, but these will likely need sterilisation doses higher than are likely to be approved at present.

Quality images for irradiated foods are being developed as part of the lobbying process to permit food irradiation use in Britain. It is essential to this image that the public accept unqualified assurances about safety and wholesomeness. The idea that, unlike many other processes, irradiated foods are unadulterated by chemical additives is also being promoted. This is misleading. As we have shown, additives will be needed to reduce undesirable changes resulting from irradiation.

CONSUMER ACCEPTANCE

There is a very real fear that consumers may not accept irradiated foods for whatever reason. This is nowhere more apparent than over labelling of irradiated foods and food products.

The EEC directive makes it difficult for UK and European interests to argue against labelling. The form this labelling will take is however still to be decided.

Dutch and South African companies use the RADURA label and call it "the emblem of quality." Given what is known about nutritional losses in irradiated foods this is highly misleading.

In the U.S., companion bills have been introduced into both houses of the congress that would ban the labelling of irradiated foods anywhere is the U.S. These bills also seek

to prevent undivided states passing local laws requiring labelling of irradiated food.

Clearly the whole issue is emotionally charged. Consumer acceptance is a vital issue that, perhaps more than any other, will affect the economics of food irradiation. In view of the nutritional and other effects of irradiation, it is vital that consumers have access to information at the point of sale about all irradiated foods. Not merely pre-packaged foods but those sold loose and in bulk (and the irradiated contents such as flours and spices in processed foods). It is arguably also in the long term interests of food manufacturers and growers to have clear labelling. Anything less than whole hearted willingness on this score will only add to suspicions that the industry has something to hide, and so compound the problems of getting public acceptance of the process.

SOCIAL COSTS

It is unclear that there are to be any serious economic advantages from irradiation of foods. Such advantages as there might be are likely to benefit manufacturers or large retailers by enabling further concentration of market control. Already smaller manufacturers, producers, and retailers are being squeezed out. This process, while allowing some consumers to benefit, reduces the range of choice to many others. Loss of retail outlets reduces accessibility of food products to the poor, elderly and others less able to take advantage of supermarket shopping. (78)

Benefits to food suppliers; the growers, manufacturers, wholesalers and retailers from irradiated foods are that they can be stored longer. This can help reduce wastage. It can also eliminate the need for some labour. The process described earlier, for low dose irradiation of meats, would not only extend shelf life, it would allow centralised preparation of meat cuts eliminating the need to do this at the local shop or supermarket meat counter. The general ability to concentrate activities on a few large enterprises is likely to result in a reduction of the number of workers employed. The costs of unemployment are passed on to the community as a whole. Any detailed study of the economics of food irradiation should take account the changing patterns of marketing and employment in the food industry and balance direct economic benefits, if any, against such social costs.

6) IS FOOD IRRADIATION NECESSARY?

What is emerging is a picture of a process that, far from providing a solution to problems of food preservation, would be only one more step in a variety of food processing techniques; heating, refrigeration, use of chemical additives, reduction of oxygen and moisture, packaging and hygienic handling. Irradiation actually adds to the complexity of food processing because it creates undesirable changes in the food. Many of the other techniques are necessary to reduce this radiation damage. It is perhaps worth asking the fundamental question whether irradiation is necessary at all.

The answer to this is by no means clear cut. In the area of low doses there might be a justification for irradiation but even here the overall benefits are by no means obvious.

Many fruits do not irradiate well, however irradiation may produce less damage to the food (and be less harmful to health of workers) than some chemical fumigation treatments for controlling insect infestations. This can be important where quarantine arrangements exist (eg in the US to control the mediterranean fruit fly). Other uses appear to have more to do with the ability of the food industry to stockpile or to deliver an apparently acceptable product for sale when long distance shipments are involved. The benefits to the consumer in this area appear to be marginal, particularly when the effects on wholesomeness and nutritional value are considered.

Irradiation of grains to control infestation may also require control of atmosphere and temperature. Packaging is needed to control reinfestation. Under these circumstances it is hard to see that there will be clear cut economic benefits that could not be derived if these other techniques were introduced alone. By far the greatest food losses occur in the warm moist and less developed countries which lack the capital to invest in such storage technology. Food irradiation with its very high capital costs and complex technology rooted in the nuclear industry would seem to be the last of a series of measures that should be undertaken to improve the situation in these countries. To propose it seriously as the solution would inevitably mean that control of the food reserves of these countries would come even more under control of multinational agribusiness than they already are. But then maybe that is precisely why it is being proposed.

In the medium dose range we enter the area where the possibilities of detrimental effects outweighing benefits becomes even greater. The major use in this area is to reduce the number of microorganisms that cause food spoilage in meats in particular. Reduction, not elimination is the goal. In the case of reduction of salmonella risks, we have seen the possibility of creating other more serious health hazards.

Irradiation does not eliminate the need for refrigeration and packaging. At least one author has questioned whether, its use is warranted

> "The doses involved ... exceed the threshold doses for irradiated flavour development in meats if done above 0 degrees C. Irradiation at sub freezing temperatures would overcome this. However, in view of the rather large costs that would be involved in such processing, including; freezing, irradiation and thawing, **it seems unlikely that a meat processor would undertake it voluntarily**. While government regulations could impose radicidation, the risk benefit balance for the consumer would need to be considered. In terms of the costs to the consumer it appears to this author, to be an unwarranted application of irradiation."(60)

The same author goes on to point out that most parasites are inactivated by the freezing temperatures needed to prevent "off flavours" in irradiated meats anyway. The further irradiation for this purpose would seem to be unnecessary.

If radicidation (at medium doses) to reduce the level of microorganisms is of marginal benefit. Radappertisation (at high doses) is likely to be even less so. The undesirable effects in terms of food odour, creation of radiolytic chemicals, and changes in microbiological balances will be more pronounced. Refrigeration to very low temperatures (-20 to -80 degrees C), use of additives, packaging to eliminate oxygen and prevent recontamination etc. will all be essential to reduce these effects. While this will allow food to be stored for long periods, the existing methods are already able to do this to a large extent. Since these will still be needed it is unclear where the advantage lies. The application for sterile medical diets is already recognised and permitted. It is nice to be able to experiment with "space age" food techniques, but the decision to permit wholesale irradiation at these high doses should surely follow clear evidence of need particularly as the technology introduces a number of distinct problems and hazards.

At the present time high dose applications are not being considered for approval. Serilisation by irradiation alone appears likely to cause more problems than it will solve.

Irradiation can be used to reduce the heat required for sterilisation just as heat can be used to reduce the amount of radiation needed. It may be that some combination of heat and irradiation treatment could overcome some of the disadvantages of irradiation, though the overall balance of risks and benefits is far from clear.

7) REGULATION AND MONITORING OF FOOD IRRADIATION

There is no easy way to detect whether most foods have been irradiated, and if so how many times and with what doses. The only effective control is at the point of processing. (17) Doses and the conditions such as temperature, packaging, and atmosphere modification all need to be tightly controlled if the undesirable effects identified above are to be avoided.

For these reasons it is reasonable to expect a much greater control over irradiation than usually required for other food processes. In general irradiation of food is not permitted in Britain. The framework of controls needs to be established before there is any change in this effective ban of food irradiation.

The current regulations would allow an extension of the existing limited permits for medical diets to other food with the requirement only that records are kept of the doses given to the food.(8) This is clearly inadequate. If irradiation is to be permitted at all, a whole new set of regulations will be needed. These should specify maximum and minimum doses and other relevant conditions for each approved foodstuff.

There is also the difficult question of labelling. The 1979 EEC labelling directive requires that the process used to treat a food be included on the label. A reasonable interpretation of this directive is that irradiated food needs to be labelled as such. Since low dose uses will affect foods such as fruit and vegetables that are normally sold as "fresh" it is vital that the labelling requirement is extended to all irradiated foods and not just packaged foods.

It is worth noting that companion bills have been introduced in both houses of the US congress that would BAN the labelling of irradiated foods anywhere in the US. These bills also seek to prevent individual states from passing local laws requiring irradiated food to be labelled. (62)

Misleading labelling is almost as bad as no labelling. Symbols like the RADURA, "emblem of quality" label, used for South African and Dutch irradiated foods should not be considered. It may even contravene the Trades Descriptions Act in Britain. Irradiated food should carry in clear and unambiguous terms the label "IRRADIATED". Anything less is likely to compound the problems of consumer acceptance by raising the suspicion that the food industry has something to hide.

In view of the uncertainties that exist over wholesomeness of irradiated foods, particularly at medium and high doses, the blanket clearance for irradiation up to doses of 10 kGy suggested by the WHO FAO IAEA would be unwise at this time. If irradiation is permitted at all, clearance should only be given for low dose applications and for specific foods. In each case the maximum and minimum doses and the surrounding conditions should be clearly specified and a certification system established that will follow the food from irradiation to point of sale.

There is an even more difficult problem in the case of food offered for sale through catering outlets. The right to know and make informed choice should apply here also.

These conditions for permitting irradiation of food should also be applied to all food imported into and traded within the European Community.

As indicated above there is also the need for companion legislation that would control the use of harmful additives and drastically reduce the maximum permissible doses of radiation to workers.

The impact of any decision to permit irradiation of food extends beyond the concerns of consumers and workers. Siting of an irradiation facility can have consequences for a local community. The very presence of large quantities of radioactive material is a cause for concern. In addition, the transport of the radioactcive material to and from the facility needs to be considered.

Public consultation and much greater access by locally elected representatives to information on the movement of radioactive material is needed. Strict licencing of the design and operation of irradiation plant also needs to be considered.

As well as the regulations, we need to consider the question of monitoring and enforcement of the legal requirements that are laid down to ensure that they are being obeyed.

Monitoring of food in the UK is currently undertaken by a combination of Environmental Health Officers, Trading Standards Officers and Public Laboratories. These are under control of District and County Authorities. Food regulation is based on the desire to prevent rather than respond to food problems.

Inspection of industrial premises on the other hand falls under the Health and Safety Executive's Factory Inspectorate. With irradiation plant the Radiochemical Inspectorate will also have a role to play in monitoring the use of radioactive source material and control of radioactive wastes. Who will be primarily responsible for enforcing the conditions under which irradiation takes place?

It is unclear who is to undertake the different monitoring roles and at what levels. It is also unclear what coordination and overall supervision will be established. Clearly the public health aspects should be the major concern. If this is to be possible, what training and new facilities are to be made available to EHO's and Trading Standards Officers? If other agencies are to be involved how will these be integrated into the monitoring system so that the priorities of protecting health of consumers and workers is maintained?

The Health and Safety Executive has not only failed to reduce the dose limits for workers but is in the process of implementing new regulations that would be less stringent than those currently in force. Other bodies associated in the public mind with the nuclear industry do not inspire public confidence. Given the problems that the irradiation of food will face in gaining public acceptance, it is vital that a clear and integrated regulatory system is established that gives priority to the agencies with traditional responsibilities for public health. This needs to be established before the present ban is removed.

8 - SUMMARY OF CONCLUSIONS AND RECOMMENDATIONS

In view of the concerns set out in this report, **any move to permit food irradiation should be preceeded by a full public consultation and the drafting of new legislation to meet these concerns. The 1972 food (Control of Irradiation) regulations should not be used as the basis for any further permits for food irradiation in the U.K.**

There is also a need for European wide legislation to harmonise the national regulations on irradiation of food. Such legislation should at the present time be in line with the best national legislation. There should be European wide controls on the importing of irradiated food from other countries.

THE RIGHT TO KNOW

The consumer has a fundamental right to know about the processes that have been used to treat, prepare and preserve the food he or she is buying. Hence **all irradiated foodstuffs need to be labelled as "irradiated" in clear and unambiguous terms at the point of sale.**

This condition should apply to bulk food, food normally sold loose or unpacked, and foods offered for sale in catering outlets, and should apply to any ingredients of these foods that may have been irradiated.

FOOD HYGIENE

Irradiation can never be a panacea for food hygiene problems. It can, at best, be used to accompany existing processes to protect and prolong the wholesomeness of various foodstuffs. Recontamination due to poor hygiene can still occur after irradiation, and to this extent, irradiation may produce a false sense of security.

It is also possible for irradiation to kill off some bacteria that serve useful functions while leaving others, more harmful, behind.

Food irradiation must not, therefore, be introduced to conceal or compensate for poor quality or poor standards of hygiene in the manufacture and handling of food.

NUTRITONAL QUALITY

Food irradiation is known to deplete the nutrient content of some foods.

These losses can be particularly serious in the case of some vitamins.

Nutritonal losses will most affect those least able to take compensatory measures - those living in "Third World" countries, and those reliant on low income diets in industrial nations.

The full nutritional impact of irradiation on the diet has not yet been assessed. Further studies in this area are needed before authorising its use in the UK.

IRRADIATION AND ADDITIVES

Irradiation is being offered as an alternative to use of chemical treatments and additives (particularly preservatives and pesticides). Some of these are known to be harmful to workers in food handling and to consumers. In practice it is likely that irradiation will be used in conjunction with many additives. **Therefore, the introduction of irradiation should be linked to legislation banning or restricting the use of other harmful additives.** Failure to link introduction of irradiation with restriction on other additives will merely increase the number of potentially harmful processes.

TESTING OF THE PRODUCTS OF IRRADIATION

The testing of the radiolytic products created in foodstuffs as a result of irradiation should be no less strict, and arguably stricter, than the testing currently required for food additives.

European wide studies to isolate and subject these products to long term safety tests should be undertaken to identify any biologically harmful effects. These should also consider the combination effects with packaging materials and permitted additives and the results be fully considered before irradiation is permitted on food for public consumption in Britain.

DOSE CONTROL

If irradiation is to be permitted at all, in the first instance, only low dose irradiation processes (less than 1 kGy) should be licenced. Doses given to each foodstuff should be within strictly controlled maximum and minimum dose limits.

STANDARDS FOR WORKER EXPOSURE

The current limits for occupational exposure represent levels of risk that would be unacceptable in any other industry. These limits should not be used as the basis for design of irradiation plant.

The current regulations for worker exposure should be revised so that all occupational exposures are limited to less than one tenth of the current maximum premissable exposure. Irradiation facilities should be designed so that occupational

exposures to all workers are limited to less than this lower limit.

These, and other stringent practical procedures to limit worker exposures to the lowest practical level should be included in the licencing process for irradiation facilities.

SITING OF IRRADIATION PLANT

In addition to radiation hazards to workers, the community faces additional radiation hazards from the plant and the transport of the highly radioactive material used in the irradiation process.

For this reason the siting of irradiation facilities should be the subject of strict licencing.

It needs to be remembered that a large number of small doses can cause the same or even greater damage to health than if the same total dose were given to only a few people in much larger doses. Public involvement in the siting of all hazardous facilities in the community is essential.

COST AND ECONOMICS

It is implied that extended shelf life will result in economic savings. Distributors will be able to hold larger quantities with less likelihood of spoilage and waste. These savings will not automatically be passed on to consumers. The benefits are more likely to be used to enable food manufacturers and/or large retailers, to increase their power and control over the food market.

High capital costs for irradiation facilities, plus transport to and from these facilities are likely to absorb many of the potential savings. The long term effect is likely to be higher prices.

Studies are needed on the impact irradiation technology might have on the economics of the food industry and on patterns of marketing and consumption.

Consumers and public authorities have a right to demand that technological innovations in the food industry bring with them real economic advantages that are actually passed on to the public in terms of lower prices or more wholesome products.

EMPLOYMENT

It is also important to consider the impact of irradiation technology on employment. Some jobs will be created in the irradiation facilities. Many more may be lost in other sectors of the food industry. These unemployed workers represent the social costs (bourne by the whole community) that may result from introduction of irradiation.

In considering the possibility of permitting commercial scale irradiation of food in Britain, research needs to be done into the impacts on employment and the social costs that might thereby result.

MONITORING

Monitoring of food in the UK is currently undertaken by a combination of Environmental Health Officers, Trading Standards Officers, and Public Laboratories.

It is unclear who is to undertake the monitoring of the irradiation process and the food that will than be offered for sale. If it is to be undertaken by the agencies above, what training and new facilities are to be made available? If other agencies are to be involved, how are these to be integrated into a system that has as its first priority protection of the consumer by prevention whenever possible?

No new process such as irradiation should be introduced until there is a clear and integrated regulatory system in place. This needs to include licencing of facilities, standards for wholesomeness and labelling, monitoring and enforcement covering all aspects of irradiated food. It also requires the training and preparation of the staff in the various agencies involved.

9 - WHAT YOU CAN DO

This report on Food Irradiation should be read alongside the government's advisory committee report. You should decide for yourself whether the issues of concern have been adequately dealt with by the committee.

If you think they have not

1. You can write to your Member of Parliament and ask him or her to oppose any attempt to remove the current ban on irradiated foods until these issues are dealt with.

2. Write to your Member of the European Parliament asking him or her to seek a European wide moratorium on any new food irradiation developments until outstanding issues are resolved.

3. Write to your local authority (Chief Environmental Health Officer, your local councillors and the Chief Executive c/o the local town hall or district/county offices). You could also write to your county councillor - if you still have one. You could ask for a moratorium on local authority purchasing of irradiated foods for canteen services, school meals, hospital catering and meals on wheels.

4. A very effective way of lobbying would be to write to the managing directors of leading supermarket chains (see contacts list below for head office addresses).

   You might also write to the manager of the local supermarket.

   Ask what their policy is and seek assurances that they will not stock irradiated foods until all the issues of concern have been dealt with. Ask for assurances that if irradiation is permitted they will clearly label it as irradiated.

5. Write to your union. Ask if there is a policy on irradiated foods, and what information and advice is available to members.

6. Watch out for any signs suggesting that irradiated foods are being marketed locally. Irradiated foods are not legal in Britain at the present time. There is no way that illegally imported irradiated foods could be detected unless they are labelled. Exotic South African fruit, such as papayas, or potatoes, onions and garlic from Europe could easily be irradiated. Ask questions about the origins of such foods. Merely asking about whether they have been irradiated will alert the retailers to what is going on. Ask to see packaging that food came in from the wholesaler.

Report any examples of violations of the ban on imports to your M.P. and to your local authority.

7. Talk about the issues raised in this report with relatives friends and neighbours. The best and perhaps only way that the issues are going to be dealt with is by widespread public interest and informed challenges to the idea that we should "trust the experts" on the acceptability of irradiated foods.

CONTACTS

The following organisations and contacts may be useful to you in seeking information or action on issues that concern you about food irradiation.

LONDON FOOD COMMISSION,
PO Box 291, London, N5 1DU, (01) 633-5782

Sir Arnold Burgen
Chairman, Advisory Committee on Irradiated and Novel Foods,
c/o DHSS, Alexander Fleming House, Elephant and Castle,
London, SE1

The Rt. Hon. John Selwyn Gummer
Minister of State for Agriculture Fisheries and Food,
Whitehall Place, London, SW1

The Rt. Hon. Barney Heyhoe
Minister of State for Health
DHSS, Alexander Fleming House, Elephant and Castle,
London, SE1

Your Member of Parliament, House of Commons, London, SW1

Your Member of the European Parliament
c/o 2 Queen Anne's Gate, London, SW1

The following MP's and MEP's are known to be interested and/or concerned about this issue.

Frank Cook	MP	House of Commons, London SW1
Tony Lloyd	MP	
Dr Jeremy Bray	MP	
John Home-Robertson	MP	
Tom Pendry	MP	
Brynmor John	MP	
Robert Mc Crindle	MP	
Carole Tongue	MEP	c/o 2 Queen Anne's Gate,
Mike Elliott	MEP	London SW1
Glyn Ford	MEP	
Ken Collins	MEP	
Richard Balfe	MEP	
Madron Seligman	MEP	
Win Griffiths	MEP	
Gordon Adam	MEP	
Norman West	MEP	
Llewellyn Smith	MEP	
Les Huckfield	MEP	
Stephen Hughes	MEP	
Richard Cottrell	MEP	
Caroline Jackson	MEP	
Andrew Pearce	MEP	
Alexander Sherlock	MEP	

FOOD MANUFACTURERS

The Food Manufacturers Federation,
6 Catherine Street, London, WC2

Unilever PLC, Unilever House, Blackfriars, London, EC4P 4BQ

Imperial Foods Ltd,
Clifton House, Goldington Road, Bedford, MK40 3NF

Associated British Foods PLC,
68 Knightsbridge, London, SW1X 7LR

J Lyons and Co Ltd, Cadby Hall, London, W14 OPA

Dalgety Spillers, 19 Hanover Square, London, W1R 9DA

FOOD RETAILERS

J Sainsbury PLC,
Stamford House, Stamford Street, London, SE1 9LL

Safeway Food Stores Ltd, Beddow Way, Aylesford, Kent, ME20 7AT

Tesco Stores Ltd, Tesco House, Delamare Road,
Cheshunt Waltham Cross, Herts, EN8 9SL

Waitrose Ltd, 4 Old Cavendish Street, London, W1A 1EX

Fine Fare Ltd,
Gate House, Fretherne Road, Welwyn Garden City, Herts

Asda PLC, Asda House, Britannia Road, Morley, Leeds, LS27 OBT

Argyll PLC, Millington Road, Hayes, Middlx, UB3 4AY

Marks and Spencer PLC,
Michael House, Baker Street, London, W1A 1DN

Spar, 32/40 Headstone Drive, Wealdstone, Harrow, Middx, HA3 5QT

Mace Line Marketing Ltd,
Gerrards House, Station Road, Gerrards Cross, Bucks, SL9 8HW

Cooperative Wholesale Society, New Century House,
PO Box 53, Corporation Street, Manchester, M6 4ES

OTHER ORGANISATIONS

London Hazards Centre,
c/o Polytechnic of the South Bank, 103 Borough Road, London SE1 0AA

Radiobiology Dept, St Bartholomew's Hospital Medical School, Charterhouse Square, London, EC1

The Microbiology Dept, University of Surrey, Guildford, GU2 5XH

Food Policy Unit, Manchester Polytechnic, Hollings Faculty, Old Hall Lane, Manchester, M14 6MR

Institute of Environmental Health Offices,
Chadwick House, Rushworth Street, London, SE1 0QT

Consumers in the European Community,
24 Tufton Street, London, SW1

The Consumers' Association, 14 Buckingham Street, London, WC1

Friends of the Earth, 377 City Road, London, EC1 VINA

Greenpeace, 36 Graham Street, London, N1

The Radiation and Health Information Service,
27 Windsor Road, London, N7

The Public Health Group of The British Society for Social Responsibility in Science and the Socialist Environment and Resources Association,
c/o SERA, 9 Poland Street, London, W1V 3DG

The Bakers, Food and Allied Workers Union,
Stanborough House, Great North Road, Stanborough,
Welwyn Garden City, Herts, AL8 7JA

The General, Municipal, Boilermakers and Allied Trades Union,
Thorne House, Ruxley Ridge, Claygate, Esher, Surrey, KT10 0TL

The Transport and General Workers Union,
Transport House, Smith Square, London, SW1

The Association of Scientific, Technical and Managerial Staffs,
79 Camden Road, London, NW1 9ES

The Union of Shop Distributive and Allied Workers,
188 Wilmslow Road, Manchester, M14 6LJ

ISOTRON Ltd, Moray Road, Elgin Industrial Estate,
Swindon, Wilts, SN2 6DU

Leatherhead Food Research Association, Randalls Road,
Leatherhead, Surrey, KT22 7RY

10 - REFERENCES AND FURTHER READING

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6. Codex Alimentarius Commission. FAO/WHO, REPORTS OF THE EXECUTIVE COMMITTEE OF THE CODEX ALIMENTARIUS COMMISSION. UNITED NATIONS 1978 AND 1981.

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COALITION TO
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National Nutritional Foods Association

STATEMENT

OF THE

NATIONAL NUTRITIONAL FOODS ASSOCIATION

ON H.R. 696

November 18, 1985

Prepared by: Burton Kallman, Ph.D., NNFA Standards Coordinator
Bernard Fensterwald, III, Legislative Counsel

The National Nutritional Foods Association appreciates being given the opportunity to testify before the House Agriculture Subcommittee on Government Operations concerning a food preservation technology -- irradiation -- whose time, we fell, has not yet come because of unanswered safety and nutritional issues. Therefore, the NNFA urges the subcommittee not to pass H.R. 696 for some very good reasons.

INTRODUCTION

Initially, we believe that the public has the right to know the nature of its food supply and the steps taken to process it. Its safety and wholesomeness must be kept as the uppermost criteria in determining the future of food irradiation. For this reason, we urge the Congress and FDA to move slowly in the approval of food irradiation and to do the testing necessary to insure its safety. As an adjunct to this fundamental concept, we submit that any use of food irradiation must be disclosed to the public through proper labeling.

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INADEQUATE TESTING

We in the NNFA believe that the irradiation process has not been adequately studied to trust its safety. A.E. Olson, of the U.S. Department of Agriculture, recently said, in the proceedings of the Second National Conference for Food Protection, May 1984, about ionizing radiation:

> As this process becomes important in the preparation of a particular food, studies should be undertaken on the possible formation of toxic compounds in that food and the effects on the processing on nutrient bioavailability. Particular attention should be directed to the possible formation of any previously unidentified compounds in that food and how they may affect food safety and nutrition.

We doubt that Olson's criteria have been fully met in the short period of time that has elapsed since he made that statement. In fact, safety testing of irradiated foods has produced over the years a number of conflicting results.

For example, one important study indicated that chromosomal changes occurred in the white blood cells of malnourished Indian children who were fed irradiated wheat. Although this study has been criticized, it has not, to our knowledge, been refuted. (Bhaskaram, Amer. J. Clin. Nutr. 28, 130-135, 1975)

Additionally, a major series of feeding studies have been conducted which utilize chicken sterilized at high dosages of irradiation. The first, a long term project involving rats fed with sterilized chicken were called off prior to completion due to excessive mortality which was not diet=related. Another study, involving the feeding of dogs over a two generation period, indicated lower body weights in a group of males fed irradiated chicken, but no other signs of toxicity. In a third (three-generation mouse) study, gamma-irradiated chicken reduced survival and appeared to produce a high incidence of tumors. These results have been challenged on the grounds of a claimed choice of inappropriate statistical methods, exaggerated by an increased unexplained death rate in the females of this group of animals. While we have not submitted these studies and the others cited in our testimony at this time, we will be glad to do so if the Committee wishes

Still another study raising serious questions about the health dangers of irradiation is a genetic study with drosophila (common fruitfly), which showed a reduced number of offspring in cultures raised on gamma-irradiated chicken. These results were

dose-related and were not reversible with vitamin supplementation.

In reviewing all of these studies, Dr. Donald W. Thayer of the Food Safety Laboratory, Eastern Regional Research Center, U.S.D.A., concluded:

> Irradiation processing of foods can produce many potential benefits, but it is not a panacea or a process free from concern. On balance, the studies of radappertized chicken conducted by the U.S. Army and various contractors strongly support the process' safety, but there are some potentially serious adverse results which must be considered when the FDA examines these studies.

(Thayer, Cereal Foods World 29, 353-356, 1984)

IRRADIATION REDUCES NUTRITIONAL QUALITY OF FOOD

Additional scientific studies have shown that irradiation can lead to the destruction of unsaturated fatty acids, which are required for the normal structural integrity and functioning of cellular membranes. These studies used the fatty acids of fish oils as targets of irradiation. As the Subcommittee is undoubtedly aware, dietary fish oil fatty acids have gained widespread attention, both in the scientific-health community and in the media, and research is currently underway into their application as protective agents against heart disease.

In these irradiation studies, it was found that specific amino acids are called upon to protect against the appearance of lipid peroxides in food, during and after irradiation. This demonstrates that vital nutrients, which probably play a similar protective role in nature, are artificially depleted during the irradiation of food. (Work on Fish Oil Lipids/Irradiation by E.C. Wills, Int. J. Radiat. Biol. 37, 383-401 and 403-413, 1980)

Ionized radiation damages living cells through radio-chemical reactions, many of which involve the production of radiolytic, highly reactive oxidizing agents. Therefore, anti-oxidants occurring naturally in foods undergoing irradiation are chemically consumed in reactions with these radiolytic products. Overall, the amounts of ascorbic acid, toconherols (vitamin E), B-Carotene, other vitamins and minerals, and certain amino acids naturally contained in food will be reduced. These reductions occur in proportion to the radiation dose and operating conditions such as temperatures and the amount of oxygen present. While low temperatures and low oxygen levels can lower the degree of destruction of these food components, both low temperature processing and deoxygenation will

significantly increase the cost and energy requirements of irradiation, which will, in turn, make the entire process less attractive commercially. With or without such precautions, we face a significant reduction in prctective materials which have been present in foods throughout evolutionary time if we allow for the wholesale irradiation of food. A biologist must conclude that these protective materials have served a purpose in insulating humans from natural radiation and from naturally-occurring oxidative toxicants. Why should we lower our actual defenses at a time when environmental pollutants and carcinogens are on the rise? Clearly, such a move is not in the best interests of the public.

Intensive scientific investigation and public interest is currently being given to these naturally-occurring protective agents against degenerative disease and some aspects of the aging process. Prudent diets emphasizing these agents have been recently recommended by a number of government agencies, including NAS/NPC, NCI, and USDA/FDA, the American Cancer Society and the American Heart Association.

What these studies suggest is that, while the right hand is making advances in the protection of society through enhanced nutrition, incredible as it may seem, the left hand is advocating the large-scale introduction of a food processing technique which specifically destroys many of these protective nutrients.

The need for an exact quantification of nutrient loss and for strict supervision of commercial irradiation procedures is apparent. A study of the mutagenicity of irradiated juices and sugar solutions showed that irradiated fruit juices were not as mutagenic as irradiated sugar solutions, because of the presence of natural protective substances in the fruit juices. The authors of this work concluded, therefore, that irradiation is safe in part because radiation doses in commercial use would be lower than their experimental doses. It must be pointed out, however, that their work did indicate that some nutrient depletion would be expected and that it is very closely related to dosage and the amount of oxygen present. (Report by Niemand, et al., J. Agricultural & Food Chem. 31, 1016-1020, 1983)

This same concept is further brought out by Simic, et al., in a recent paper entitled "Radiation Chemistry -- Extravaganza or an Integral Component of Radiation Processing of Food," (Radiation Physics Chemistry, 22, 233-239, 1983) in which the authors attempt to reach a balance between the proponents of irradiated foods. To quote directly, there are those who.

> . . . would like to see unquestioned approval of irradiated foods. Some demand acceptance, in totality, of radiation processing without ever having to reevaluate its safety. There are, on the other hand, groups who like to see 'dissection'

> or irradiated foods down to infinitesimal components such as isolation of all radiolytic products and safety testing of all those not present in standard foods.

Rather, Simic, et al., conclude that the proper answer is to continuously re-examine the safety and improve the quality of irradiated foods. They point out that the radiation-induced free radical reactions which occur in irradiated foods are responsible for all the biological and chemical effects, desirable or undesirable; that they produce a variety of radiolytic products; and that they are dependent on dose, dose rate, temperature, atmosphere, physical state and extent of hydration.

CONCLUSION

The NNFA agrees with Thayer and Simic and his coworkers. We believe that continuous evaluation of irradiation is mandatory. We believe that continous monitoring of the processing specifications and operating conditions are mandatory. We doubt that extrapolation from the animal studies done to date, and from the limited use of irradiated foods by astronauts and cancer patients, can be used for accurate predictions of safety and nutritional adequacy by the entire diverse population of our nation, especially down the road twenty years when a large portion of our diet has been irradiated.

The National Nutritional Foods Association has issued a position paper affirming its opposition to the concept of food irradiation and to further extension of the use of this process. A copy of this is attached hereto.

We have also strongly endorsed labeling of irradiated foods at point of sale. American consumers have a basic right to know what they are purchasing. When they buy and use food treated by canning, pasteurization, freezing, pickling, dehydration, salting, etc., they have a reasonable knowledge of how that food has been treated. There is no special reason that we are aware of that creates special treatment for irradiation and mandates that its use be kept secret.

Instead, we support full disclosure and consumer education on the subject of irradiation -- the cumulative environmental and health risks as well as projected economic benefits, the real costs to individuals and communites as well as the potential gains for industry and government.

Irradiated food was recently banned in Great Britain and is illegal for domestic consumption in West Germany. Not everyone is jumping on the bandwagon for irradiating the food supply of the world.

Let us not rush into a decision with irreversible effects on generations to come for our love of advanced technology. Let us keep foremost on our conscience our love for the welfare of mankind.

National Nutritional Foods Association

CONSUMERS, RETAILERS, WHOLESALERS, GROWERS AND MANUFACTURERS ... OF THE HEALTH FOOD INDUSTRY
151 EAST BAKER AVENUE, SUITE 210, COSTA MESA, CA 92626 • (714) 966-NNFA

JULY, 1985 POSITION PAPER: FOOD IRRADIATION

The U.S. Food and Drug Administration is proposing to allow the preservation of fruits, vegetables and grains by irradiation at dosages up to 100,000 rads. Present plans are that irradiated foods will not be labeled as such at the retail level. The National Nutritional Foods Association (NNFA) questions the safety of irradiation and believes that any food subjected to irradiation must be so labeled. This belief is based on uncertainties in the program of safety testing these foods, uncertainties in the extent of nutritional losses in these foods, and perhaps most importantly, on the basic right of all humans to be fully informed about the products they are consuming. Each of these areas will be discussed briefly:

1. Safety Testing

Irradiated foods have been tested for safety in many different laboratories, under many different conditions. Some studies have been discredited. One animal study showed adverse effects of irradiated foods but a later statistical analysis led to reversal of this conclusion. What would a still later statistical analysis have concluded? A study with malnourished children has shown genetic changes in white blood cells after consumption of irradiated wheat; similar studies with rats have both confirmed and refuted this finding. NNFA believes that it is beyond the ability of any scientist or regulator to extrapolate from the existing animal data to a realistic risk for all humans consuming irradiated foods over an entire lifetime.

2. Nutritional Losses

Many studies of the chemical changes which occur in irradiated foods have concluded that protective substances in the food are used up in destroying highly reactive radiochemical products. These protective substances, which may include certain amino acids, anti-oxidants, vitamins and other materials, are part of our normal food intake and are important nutritionally. The extent of their disappearance will depend on the operating conditions of irradiation and minimizing this loss will require greater expense to the operator. Under any conditions, we believe that it is presently impossible to predict with acceptable confidence that 30 or 40 years of consuming such depleted foods will have no effect on all human populations, regardless of genetic makeup, occupation and personal habits.

3. Right to Know

With the above points in mind, we especially believe that consumers have the right to be informed that a food has been irradiated or contains significant amounts of irradiated components. It is argued by some proponents of irradiation that other types of food preservation are not indicated on product labels. This is a specious argument. The consumer who purchases food preserved by canning, freezing, pasteurization, salting, dehydration, pickling, etc. has a good idea of what has been done to that food. No less should be required for irradiation.

In summary, the National Nutritional Foods Association reaffirms its opposition to the concept of food irradiation and endorses the position that further government or commercial food irradiation be discontinued or that at least immediate steps be taken to adequately inform consumers which products in the marketplace have been subjected to this process.

STATEMENT OF CLINTON RAY MILLER

LEGISLATIVE ADVOCATE OF THE
NATIONAL HEALTH FEDERATION

BEFORE THE HOUSE
AGRICULTURE SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE

ON

H.R. 696/S. 288

NOVEMBER 18, 1985

Mr. Chairman and distinguished members of the Subcommittee:

Thank you for allowing me to appear at this important hearing to offer comments and amendments of the National Health Federation on H.R. 696/S. 288.

My name is Clinton Ray Miller. For 23 years I have been the Legislative Advocate for the National Health Federation. NHF is a 30-year-old national consumer organization of responsible, aware, environmental, health and fitness minded activists who take very seriously our mutual responsibility for the safety and wholesomeness of the food we eat.

We have learned by sad experience we cannot delegate this responsibility to state or federal bureaucrats who are often on their way through a revolving door into or from high paying jobs in the very industries they are supposed to regulate.

In 1962 we "fathered" and won virtual unanimous approval of NHF's "Human Guinea Pig Amendment" which, for the first time in recorded history, prevented any further medical experimentation on humans without their informed consent. This NHF Amendment has fundamentally changed the practice of medicine not only in the U.S. but throughout the civilized world.

The proponents of food irradiation want us to participate in an unprecedented massive medical experiment without our knowledge and consent.

Members of the National Health Federation and increasing millions of other individuals are deeply concerned that eating "irradiated food" is still in the experimental stage. NHF agrees with Sanford A. Miller, Director of the U.S. Food and Drug Administration's Center for Food Safety and Applied Nutrition, who stated when asked if he felt irradiated foods should be labeled:

> "Yes, I personally do. The department may have another view on this, and there actually are some good reasons why you shouldn't have to do it...My own feelings are that it should be labeled, and when it's said and done, I think it will be." (enphasis supplied)

The NHF is unalterably opposed to H.R. 696 (S. 288) in its present form. Unless it is drastically amended we will do all in our power to urge our thousands of members and millions of friends to kill this legislation.

NHF proposes the following amendments to H.R. 696:

1. We urge you to amend out all language in this bill which declares or implies in any way that it is U.S. policy that "Congress finds that irradiation of food is...safe and wholesome." (See H.R. 696, p. 2 line 508)

Congress may pass a law STATING it is "safe" to buy, sell, transport, store, keep-track-of, use and dispose of the massive amounts of highly radioactive material which would be used in hundreds and possibly thousands of food irradiation plants - - some of which would be located near or in our largest cities - - but that doesn't make this terribly dangerous technology one bit safer than it really is.

Saying it is safe doesn't make it safe.

Congress can pass a law stating it finds the world is flat, but that doesn't bend the horizon one inch.

We therefore suggest that for Amendment #1: On Page 2, Strike out the present language on lines 5-8 and in its place insert wording somewhat as follows:

Sec. 2 (a) The Congress finds that (1) irradiation of food is a relatively new food preservation technology compared with drying, freezing and canning. The hazards or safety of consuming irradiated foods for long periods of time covering several generations is simply not known. The technology itself is extremely hazardous even if the irradiated food is found to be absolutely safe. The transportation, storage, use and disposal of radioactive material is the most hazardous technology yet used to preserved food.

Amendment #2: Remove all language from the bill which would remove food irradiation from the current statutory requirements it be regulated by FDA as a "Food Additive."

We have included as part of our testimony 6 exhibits which we respectfully request be included as part of our written statement.

Thank you for your courtesy in giving us this opportunity to testify against H.R. 696 unless it is dractically amended.

(Exhibits follow:)

EXHIBIT 1

IRRADIATION!
PART I

Add a new buzz word to your vocabulary. It is *irradiation!* The discovery of EDB in grain products—everything from pasta to pancake flour—has prompted the great commercial scientists to dust off an idea that most people literate in the subject believed bypassed and forgotten years ago. In fact, extensive literature on the subject surfaced to sour the landscape as early as the post WW II years. By the mid-1960s, scientific findings had removed irradiation from consideration as a food preservative for all except those engaged in the food business, or those trying to find a way to get rid of radioactive waste.

The late Dr. Granville Knight, once an *Acres U.S.A.* Conference speaker, had more than a passing interest in the irradiation process. As a competent physician, he pulled into orbit a great deal of literature on the irradiation process, some of which had been passed on to the Price-Pottenger Nutrition Foundation. The findings are so extensive that *Acres U.S.A.* can only present an abstract in-depth of a comprehensive wrap-up by Dr. Walter Herbst.

The best available wrap-up on the subject appeared, under the imprimatur of a German publication, *Verlagsgenossenschaft der Waerland* as an article entitled "Incalculable Health Risks by Food Irradiation." Herbst, in turn, drew on dozens of scientists who stated the case presented as the backbone of this article.

BACKGROUND

According to several scientists, the real impetus behind the irradiation concept is the fact that industrial society now has a fantastic accumulation of radioactive waste from nuclear plants. This waste product, for which no suitable disposal system has been found, is ready in the wings as a cheap source of irradiation energy. As radioactive waste continues to accumulate, those associated with both the food and atomic industry have become more emphatic in their demands on FDA. In short, those responsible for the wholesome food supply are being pressured to release more foods for irradiation.

At approximately the time of the EDB newspaper headlines, irradiation came out of the closet in *Industrial Technology* magazine. That journal had nothing but fulsome praise for irradiation on grounds that the astronauts had made use of food preserved in that manner. *Industrial Technology* said that at doses below 1 megarad, there was no danger from radioactivity or resultant carcinogens or toxins in food.

Preservation of food without destroying nutrition has been an objective of the trades since the first cartload of vegetables headed for market somewhere in the world. Even primitives knew that food—even treated food—was subject to physical and chemical changes. Accordingly, the addition of salt, sugar and smoke has been used to kill or inhibit micro-organisms responsible for decay. Heat has also been used as an agency for preservation, always in the form of pasteurization or sterilization.

In the grain trade, insect and fungal attacks on marginal production are

costly to commerce. Much the same is true for peas, beans and dried fruit. The appearance of EDB in chain store food products recently has the earmarks of a well choreographed background dance for the introduction of irradiation.

But what is irradiation? It is now a matter of record that GIs during the wars were used as handy test creatures whenever the Svengalis of science had new super-science to offer. Food irradiation made its debut that way, with uninformed provenders marveling at how well non-foods would keep for GIs in the field. For the purpose of food irradiation, either large-size apparatus like particle accelerators and X-rays could be used, or—in most cases—physical decay of the nucleus of radioisotopes found in atomic waste and reactors were invoked.

There is a problem in this. Unlike heating and chemical processes, radiation affects the molecule in a most specific and highly interventionary manner. It establishes "excited conditions" and induces the formation of radicals, or ionization. The molecules and atoms accordingly changed are chemically highly reactive and effect specific changes, some of which are only partially effective in preserving food. But they cause qualitative changes in foods that are—depending on dose—extremely dangerous.

In any case, talk of danger is being washed away with the intelligence that a $50 million per year industry is about to be born for spice processors alone, and that the irradiation business could expand to $1 billion per annum rather promptly. All that was needed was a trip for most food through a typical $2 million irradiation chamber. Microbes would be "killed," but enzymes would be "inactivated," if one wants to note official grammar. Those who support the concept are much worried about *Clostridium botulinum*, and they offer the consolation that 80 percent less nitrates will be needed in food preservation.

The industry and the musical chair directors of FDA are already arguing that irradiation is cheap. It is.

It is not extreme to suggest that a replay of the fluoridation scenario is unfolding. In the case of fluoride, the phosphate and aluminum industries found themselves with waste that was only slightly more difficult to get rid of than atomic waste. Thus was born the bright idea of loading the toxic materials into the nation's water mains on the basis of specious scientific findings that fluoride contributed to hardness in teeth, hence less cavities.

In the case of irradiation, the surplus product that is difficult to get rid of is radioactive waste. Radioactive waste to treat a ton of potatoes, for instance, would cost only pennies, and the cost of materials to treat the rest of the groceries would be even smaller. And this is how the nuclear industry hopes to move out the tiresome waste—into thousands of food treatment facilities, into city dumps, where irradiated packages may well continue to give off their dangerous energy.

The appearance of EDB in chain store food products recently has the earmarks of a well choreographed background dance for the introduction of irradiation.

It may be that the community is willing to accept these hazards as a calculated risk. A more important question, possibly, would be: does it work?

SCIENTIFIC FINDINGS

According to German scientists, many packing materials suffer structural changes when irradiated and become permeable to air. This endangers the enclosed foods, and sometimes delivers toxic substances to the food. Still, it is argued, food irradiation helps destroy pathogenic germs in food—Salmonella, for instance, *Clostridium botulinum*, for instance. However, different types of micro-organisms vary considerably in sensitivity to radiation, contrary to heat sterilization. Some species are even more resistant to radiation than living germs. Moreover, it can happen that within one single species highly radiation-resistant biotypes are selected out, or renewedly formed by mutation, the effect being that radiation can breed an entirely new microflora. The ramifications of this finding run into too many box canyons to comprehend instantly.

Those who promote irradiation—press releases to the contrary—are not quite prepared to abandon the nitrates, nitrites, antibiotics, reducing compounds and antioxidants, chloride, hydrosulphides, ascorbates and all the rest of modern food fabrication's claptrap. Nor are they about to abandon pre-kill injections of slaughter animals. In all cases there are synergistic actions.

Actually there is nothing very new about irradiation, except that now industry has an abundance of cheap radioactive materials developed at fantastic expense to utility customers nationwide. The foundation for the procedure was put down with the

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Now that EDB (ethylene dibromide) has finally been labeled as a killer, the embalmed-food industry is pressing hard for irradiation as a food preservative. They would like to use radiation dosages in excess of 1,000 kilorads for long shelf "life." FDA studies show that if food irradiated at 100 kilorads comprises more than .03 percent of the diet, there are so many *unique* byproducts in the food that further testing should be done.—*Science*, February 17, 1984.

Unique means that food compounds are no longer food compounds. What the deleterious effects of those compounds are on the body cannot be separated from the effects of some of the hundreds of other unnatural compounds in the bodies of people and test animals. Once again scientists propose to use us as guinea pigs, having made reasonably certain that grounds for liability suits cannot be established.

There is only one way to prevent sickness and genetic mutations from destroying us, and that is to turn to locally grown fresh foods grown and processed without chemicals. There is no longer any basis for confidence in scientists generally. We can no longer tolerate the decisions of science-for-pay.—*John D. Hamaker letter.*

IRRADIATION

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discovery of X-rays by Routgen in 1895. Work with nuclear radiation by Curie and Rutherford added to the body of knowledge, as did Thomson's work with cathode rays in 1897. The arrival of the atomic age rounded out missing links in the technology for use of irradiation.

Soon after WW II in 1945, industrial firms and their captive scientific institutes in various nations, chiefly in the United States, kicked open the door. The Atomic Energy Commission marched in. By 1953 a large-scale program was started by the U.S. Army.

Soldier became uncomplaining guinea pigs. The logistics of preserved food for long patrols and field activity was perceived to offset latent danger to health. USDA joined the U.S. Army and a Canadian government-backed firm called Atomic Energy of Canada Limited, in developing basic technology. With a hotbox ready to go, all the industry now needs is approval. And the climate at FDA suggests that wholesale approval will be forthcoming. As with careless drenching of GIs with Agent Orange during the Vietnam affair, the military leaders failed to consider the consequences—or perhaps chose to ignore them.

The last statement is made advisedly. In 1966 there was a symposium on food irradiation in Karlsruhe, West Germany. Great international food agencies were invited, but those who came were mainly representatives of industry. By then the systems for irradiation were pretty well established.

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HFS

NOTE: The National Health Federation is leading a national battle to require a label on all food which is irradiated. Please send $1.00 to NHF, Box 688, Monrovia, CA 91016 for 10 NHF form letters (B-102) which ask FDA to require a label when fresh fruits and vegetables have been irradiated.

Distribute as many copies of this form letter as you can. Get all your friends to sign and mail them. (See May 1984 *Health Freedom News*, p. 26, "FDA's 'No Label Proposal.'")

THE SCIENTIFIC SYSTEM AND IRRADIATION

I have no objection to the sale of irradiated food to willing buyers—provided the buyers are not tricked into buying it (a) by false claims about its safety and/or (b) by inability to detect that irradiated food is what they are buying. In short, *I am emphatically in favor of labeling irradiated foods at the retail level as irradiated*, and I am emphatically in favor of honesty in statements issued about their safety.

From a lifetime of research in both heart disease and cancer, I know what sort of studies are required to ascertain the delayed effects and the cumulative effects on humans of biological agents such as diets, drugs, pollutants, and energy-transfers (ionizing and non-ionizing radiations). Animal studies and cell studies can provide information of only limited value about carcinogenicity, teratogenicity and mutagenicity. The kind of epidemiologic study required to find out whether or not a diet of irradiated food will increase (or possibly decrease) the frequency of cancer or genetic injuries among humans simply has not been done.

What is more, such a study is unlikely ever to be done, because it would require controlling the diets of at least 200,000 humans of various age-groups for at least 30 years, and following their health-histories for at least 50 years (preferably their full life spans).

It is probable that we shall never know whether or not irradiated foods are safe. What we do know with certainty is that irradiation causes a host of unnatural and sometimes unidentified chemicals to be formed within the irradiated foods, and that the number, kind and permanence of these "foreign" chemical compounds depends on the food itself and on the dose of radiation.

Our ignorance about these foreign compounds makes it simply a fraud to tell the public that "we know" irradiated foods would be safe to eat. The meaning of the word "safe" is not relative. Safe means "involving no risk . . . unable to cause trouble or damage." The right of free people to buy products of unknown safety, like their right to accept hazardous jobs, is matched by their right to be free from fraud, deception and trickery in such transactions. Both rights are at issue in the labeling of irradiated foods, an issue which differs from the pollution issue because purchases and work contracts are voluntary acts, whereas pollution is a coercive act which *forces* people to breathe, drink and eat substances which they cannot avoid.

The reason that it is dishonorable to trick people into buying irradiated foods (which they might otherwise choose not to buy), by failing to label them as irradiated and by making false safety claims, is because such behavior is a violation of the basic human right. The basic human right, upon which the USA was founded as an inspiration to all mankind, and which provides guidance to the FDA and to all of us on matters of honor, cannot be stated to often: *The basic human right, from which all other genuine human rights derive, is the right of every peaceable individual to hold himself and his property free from human force and fraud, provided he helps to defend the right for all other peaceable individuals.—John W. Gofman, M.D., Ph.D., in FDA testimony, February 28, 1984.*

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EXHIBIT 1, Part 2

IRRADIATION!
PART II

Add a few more words to your vocabulary: rad, krad and mrad. A rad is a physical unit for absorbed radiation. More specifically, it is the measure for the energy absorbed by 1 gram of material irradiated with energetic rays (physically corresponding with 100 erg per gram). A krad is a kilorad, and it equals 1 million rad.

As long as 15 years ago the state of the arts for food irradiation had already leveled off. For instance, it was known that it took 1 to 5 mrad to sterilize food. Virus annihilation required 5 to 10 mrad, and such a dose induced considerable qualitative losses in all treated foods, and led to the formation of toxic products in food.

Pasteurization of milk by ionizing radiation required between 0.1 and 1 mrad. Even at such low levels the process has a drastic effect on the quality of the food.

In the case of fruits, metabolic inhibition and increase of durability could be attained by partial inactivation of enzymes. Total inactivation of the enzymes took 5 to 100 mrad, but this level destroyed the quality of fruits and vegetables to a point of making them unmarketable. Thus the experts settled on 0.2 to 0.4 mrad for pears; 0.5 mrad for apples; 0.3 mrad for citrus fruits; and 0.4 mrad for strawberries.

Radiation levels for preventing insect attacks in stored wheat, peas, beans, flour, dried fruits—on and on—were established, as were levels that would presumably enforce birth control on spores in particular, and fungus proliferation in general. Some storage problems required truly great doses. In the case of Trichinella, a destructive dose amounted to 10 to 30 krad. Research revealed that in order to reduce Salmonella 10⁷ egg powder needed 700 krad, a very powerful fix.

We will not attempt to report here the names of scientists who discovered the effects of irradiation on the contents of food. The list would be too long. But the simple facts they made a matter of record can be stated with alarming brevity.

PROTEINS

Radiation in food effects the separation of lateral chains and end groups of these molecules. The separated groups include amino acids. Considerable quantities and varieties of hydrocarbons are formed, partly volatile in nature. Included in this inventory are methyl and ethyl mercaptan, dimethyl and carbonyl sulfide, hydrogen sulfide, benzol, toluol and methane.

AMINO ACIDS

Amino acids which contain fissionable lateral chains of sulfur are tremendously sensitive to radiation. Individual amino acids in foods are disintegrated in a specific manner, according to the chemical synthesis, under the influence of irradiation. For instance, phenylalanine disintegrates to form toluol and benzol. Tyrosine does the same to form phenol and cresol. From cysteine and methionine are formed sulfides, methyl mercaptan, sulfur dioxide and hydrogen sulfide. As a consequence of disintegration caused by radiation of amino acids, great amounts of carbon dioxide are released.

FATS AND FATTY ACIDS

Fatty acids are sensitive to irradiation. The quality of oil suffers enormous changes at medium radiation doses, and even more at high doses. At medium to high doses, toxic substances are developed. Irradiation of soybean oil results in a changed iodine number, a rise in the peroxide and acid values, and destruction of tocopherol (vitamin E).

LIPIDS

Lipids are very sensitive to irradiation. Under such treatment, lipids produce breakdown products, and this—in irradiated meat—accounts for repulsive odors. What happens is this: the lipid molecules are separated by radiation through dissolution of their molecular bindings. A number of radicals are formed, and these combine with oxygen to form things like hydrogen peroxide. One researcher analyzed more than 80 volatile compounds of lipids disintegrated by irradiation. Particularly numerous were the carbohydrates, which themselves can be disintegrated into highly toxic compounds when subjected to irradiation. One researcher identified no less than 15 different alkanes (saturated hydrocarbons) and 13 alkenes (unsaturated hydrocarbons). The latter were especially olefin compounds. Also found were methyl esters, methyl acetates and acetone.

CARBOHYDRATES

Carbohydrates hoisted a warning flag all their own when examined in terms of irradiation. Disintegration under irradiation produces substances which injure cell division and probably hereditary structures. Most of these

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breakdown products were chromatographically determined.

Even grade school kids know that deoxyribonucleic acid and ribonucleic acid (DNA and RNA) carry the blueprints of life. Genetic information contained in the DNA and RNA determines the basis for cell division and the life process in general. Nuclele acids are extremely sensitive to radiation, and also to irradiation products in food. Irradiated foods that offend the localites of transmission of genetic information to protein molecules are particularly sensitive to radiolysis products formed in the cells.

In order to destroy large molecular proteins with catalytical qualities outside their biological binding, high doses must be used. This is a general rule. At the same time it must be remembered that, say, a respiration enzyme transmitting oxygen in potatoes is changed by 10,000 rad. Moreover, so-called unchanged or insignificantly changed enzymes in irradiated foods often develop a high activity. Thus the enzymatic decomposition of meat is considerably increased after irradiation. This is the reason offsetting steps have to be taken with meat such as treating slaughter animals with adrenalin in order to reduce the activities of the ferments which dissolve proteins.

Irradition also destroys vitamins. The industry hopes to make an end run around this problem by adding vitamins after irradiation. Unfortunately biopotency of vitamins is affected by simply adding vitamins to irradiated food.

Most of the objectives to irradiation of food pale into insignificance when compared to the radiomimetic factor. The very process of irradiating foods forms radiomimetic chemicals. These are chemicals that ape the character of radioactivity. The farm chemicals generally are radiomimetic.

In the cell, plant, animal or human, these are chromosomes which carry almost all of the information needed to direct that cell's growth, division and production of chemicals such as proteins. These chromosomes are composed of information-bearing genes.

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IRRADIATION

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Radiomimetic chemicals (chemicals that ape the character of radiation), radiation itself, and many of the chemicals used in agriculture can injure the chromosomes either by altering the chemistry of a single gene so that the gene conveys improper information (called *point mutation*) or by actually breaking the chromosome (called *deletion*). The cell may be killed, or it may continue to live, sometimes reproducing the induced error. If it continues to live, its self-regulatory powers are often affected. Some types of cell damage may cause genetic misinformation that leads to uncontrolled cellular growth. The phenoxy herbicides all operate on this principle. In human beings the same general phenomenon is called cancer.

Cellular damage because of malnutrition or the invasion of toxicity can cost a farmer either part or all of his crop. The same damage in human beings can cost a nation its heritage and its future. Damage to the sperm or ova in a human being can cause malformation or mental retardation in future generations. It can also contribute to degenerative metabolic disease. Indeed, the United Nations Scientific Committee on the Effects of Atomic Radiation has noted: "It is generally accepted that there is a genetic component in much, if not all, illness." Researchers have determined that a group of radiomimetic chemicals, the epoxides, form up in foods as a consequence of the irradiation process.

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Commercialization of irradiation for foods has been slow because of organoleptical changes in the food due to bombardment with radiation. This means odors and flavors are depreciated by the process, and this is something the consumer will not accept. Milk and cheese have led the way in being unsalable with less than 0.1 mrad treatment. Needless to say, technology has improved, and the industry can now use chemical additives to fool the taste buds and the human smeller.

TISSUE CHANGE

There are other changes in food when irradiation is invoked. Large molecules of the cell and permeability of these walls to different ingredient substances of the cell are especially sensitive to radiation. This means that with an increase of permeability, internal cell turgor decreases simultaneously. Adhesion of cells, one to another, is reduced. Increased respiration within the cell supports detrimental changes in the texture of irradiated foods.

RADIOMIMETIC CHEMISTRY

Now, back to the business of radiomimetic chemistry. Scientific literature has accumulated a fantastic inventory of information on this, and space conservation polices suggest that only bare notes be presented:

Cell division. If potatoes are irradiated with only 20 to 40 krad and barley seedlings are cultured in the mash of such potatoes, an increase in degenerated cell nuclei occurs in the cells of the barley.—*Swaminathan, et al.* If barley and onions germinate in orange and apple juice irradiated with 200 krad, chromosome breaks are observed in these plants during cell division.—*Chopra, et al.* The effects of extracts of irradiated plants on cell division cause an increase in mitotic disturbances.—*Kuzin, et al.* Cultures of human leucocytes, to which irradiated sugar solution is added, exhibit a decrease in the rate of cell division and an increase in chromosome breaks.—*Shaw, et al, from Whitehair.*

Mutations. If Drosophilia (a fly

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species used in lab tests) are given food irradiated with only 150 krad, the number of sexually-bound recessive mutants as well as the mortality of the animals increases. Similar findings have been repeatedly confirmed.—*Swaminathan, et al; Holstein.*

Fertility. In view of more recent radiobiological results, which reveal that direct radiation has a more drastic effect on fertility assumed, it is not surprising that the fertility of the animals is reduced when they are fed irradiated food. Thus the reproduction of rats, additionally fed irradiated oranges, was disturbed in some cases.—*Phillips, et al.* The suspicion remains that if dogs are fed irradiated meat, this may cause a reduction in fertility of the animals.—*McCay, et al.*

Injuries to the embryo. Embryonal damages are almost certain to occur.

Digestibility. Irradiation generally reduces the digestibility of food.—*Schreiber, et al.*

General metabolic reactions. The consumption of irradiated foods will affect the metabolic reactions in the organism. Rats fed irradiated pork showed an increased enzymatic activity in the liver tissue.—*Read, et al; Thaisz, et al.*

Growth, vitality, mortality. A considerable number of observations on the effect of irradiated foodstuffs on growth have given room for serious doubts. For instance, a significant reduction in the growth rate of the third generation of rats, additionally fed oranges irradiated with only 140 krad occurred.—*Phillips, et al.*

Hematological and immunological processes. Hematology is the branch of medicine which has to do with blood and blood diseases. Immunology is the science which has to do with immunity and the processes which lead to immunity; i.e., resistance against infections. Since the aftereffects of the consumption of irradiated foods on living tissue are similar to those of direct radiation, the relevant problems, which include an eventual reduction of the resistance against infectious diseases, are of utmost importance and deserve due attention, European researchers report.

Changes of the organs. In dogs fed irradiated food, an increase in the weight of the spleen together with congestions in this organ, was determined. —*Larson, et al.*

Carcinogenicity. Some authors report a significant increase in malignant lymphomas in mice fed irradiated mixed feed.—*Brice, et al.*

Acres U.S.A. does not present these facts as definitive. Who knows, maybe the government has repealed the laws of physics, and atomic energy is different nowadays from what it was when most of this research was done, approximately a decade and a half ago.

But perhaps we can be pardoned for asking these questions.

Some of the same questions have been asked about radar range food, and the answers have not been forthcoming. Except for material printed in the foreign press, we have a hard time getting scientific answers to many things. We think it can be argued that Germany—the fountainhead of modern chemistry—is far from illiterate in the subject, and therefore their scientists must be taken seriously, even if circulation of this information is inimical to commercial interests in the United States.

It is probably asking for a cover-up, but we believe a Congressional investigation is indicated. The FDA's recent action that permits irradiation of food for the market is too irresponsible to go unchallenged.

So far, FDA has approved irradiation on wheat and wheat products, and on potato tubers for sprout inhibition. Approval for spices came in July 1983. Now the agency wants to permit zapping by up to 100 krads across the board. From the sound of language now being bandied about in the agencies, irradiation beyond 100 krad will arrive very soon. Industries involved will simply have to prove that 100 krads irradiation causes no genetic damage.

Such stone age science should be beneath the dignity of a developed nation—but it isn't, not when there are $2 million irradiation chambers to be sold, and when the food industry—having shoved out the farmer—suddenly tastes a $1 billion industry coming on.

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EXHIBIT 2

The WASHINGTON Report

By Clinton Ray Miller

FDA'S "NO LABEL" PROPOSAL

On February 14, 1984, the U.S. Food and Drug Administration published a Valentine proposal in the *Federal Register* announcing its intention to allow the use of radiation by food processors to destroy harmful insects and to extend the shelf life of fresh fruits and vegetables.

Under the FDA proposal, no label would be required at the retail level to warn or inform consumers that their food has been irradiated.

This "no label" part of the FDA's proposal should be strongly opposed by NHF members and friends.

A form letter has been prepared by NHF to help you quickly express this viewpoint. Please order or make extra copies of the form letter and get your friends to sign and send them in as soon as possible. Keep distributing and sending them for the balance of 1984 as though the 9 month extension we have requested has been granted.

NHF is not opposed to irradiation of food by those food companies who want to do so—provided they inform consumers, who have the right to buy irradiated foods if they want to. Equally important, but ignored, is the right of those who do *not* want to buy or consume irradiated foods. Under FDA's proposal those who do *not* want to consume irradiated foods would not be able to avoid them because there would be no way of knowing if food has been irradiated. Industry does not want to put a label on the foods at the retail level, and FDA has proposed to keep consumers in the dark by issuing a "no label" proposal.

RADIOACTIVITY IS NOT THE PROBLEM

Irradiated foods do not become radioactive at the proposed level of exposure. It is *important* for NHF members to understand this point and to explain it to their friends when they get them to sign and send form letters to FDA.

However, this does not mean that irradiated foods are not measurably changed in ways that may be mutagenic or carcinogenic.

At this stage of the game, we simply do not know the significance of the chemical changes that we know do occur. We do not have instruments which are sensitive enough to measure all of these changes.

According to FDA and HHS Secretary Margaret Heckler, this doesn't mean that we shouldn't go ahead and allow the process to be used, and it will decrease the need and use for ethylene dibromide (EDB) and other cancer-causing pesticides.

This seems reasonable *provided all the consumers who do not want to go along with the mass experiment know how to avoid buying foods that have been irradiated.*

DESTROYING IRRADIATION RECORDS

FDA's proposal would only require processing records..."be maintained and available for FDA inspection for the expected shelf life of the irradiated food product, plus 1 year, and (FDA) invites (our) comments on this proposed requirement."

Because the shelf life of fresh fruits and vegetables is usually less than a year, all records could be destroyed after two years. This would make it difficult to sue guilty parties if injury were discovered after two years.

Accurate records should be maintained for a sufficient length of time for scientists and consumers, in and out of government, to be able to study the long-term effects of consuming foods which are irradiated at various levels of irradiation.

The records should not be destroyed during the "shelf life" of the consumer and at least one generation of his or her children so scientists can check for birth defects related to consumption of irradiated foods.

Cancer, birth defects and other serious adverse reactions may not appear for several years after consuming irradiated foods. The records should be available to the press and the public, as well as the FDA.

There are no trade secrets to protect here and no justification whatever for the haste to destroy records after two years. Rachel Carson would have advised us to save them for three generations as it takes that long to determine the subtle, long-term effects of many poisons.

For good or evil, Health and Human Services Secretary Margaret M. Heckler will be remembered by future generations as the person who opened the way to irradiate the world's food supply. Heckler who made her remarks at the 77th annual convention of the

National Food Processors Association (NFPA), stated that she well knew she was making... "an announcement that has enormous importance for your industry and for the quality and availability of food here in the United States and around the world." No truer words were ever spoken.

It is easy, but proper, for those of us who are "health conscious" to criticize those who put harmful preservatives and pesticides in our food supply; with that right and duty to criticize comes the responsibility to advocate and defend safer alternatives. It is in that spirit that Heckler has advocated irradiating our food supply.

Margaret Heckler is among the most "health conscious" members in Congress. She was one of the first to co-sponsor and support NHF's famous "Proxmire-Heckler vitamin bill." She fought tenaciously and successfully for its enactment.

As a mother of 3 children, she has been deeply concerned with the increasing use of highly toxic pesticides, fumigants and preservatives. It is precisely because of this intense, ongoing concern that Heckler has turned to food irradiation as what she believes will be a safer alternative.

Award winning movies like *China Syndrome*, *Silkwood* and *War Games* have caused widespread concern about radiation.

To allay these legitimate fears and in her enthusiasm for irradiation of foods Secretary Heckler has gone far beyond the mark in her public assurance to the public that the process has been proved to be "completely safe." These are her exact words, "COMPLETELY SAFE."

In the not-too-distant past we have heard these same assurances of "completely safe" for the pesticides and fungicides like EDB that are ultimately discovered to be extremely toxic.

Heckler said in her speech to NFPA: "The amount of ionizing energy permitted under the regulation is well within the bounds of safety for human consumption.

"In fact, at the dosage levels we have established there is NO (emphasis is hers) residue from the treatment."

Now if Secretary Heckler is speaking only of radioactive residue, she is accurate. At least it is accurate to say that we cannot measure any radioactivity with our present technology.

So let's agree on that point.

NON-RADIOACTIVE PRODUCTS ARE A VALID CONCERN

Heckler made no mention whatever of radiolytic products that are produced when all foods are irradiated. These radiolytic products are "stable" and are not radioactive. This however does not mean they are safe. EDB and other extremely hazardous pesticides are "stable," meaning non-radioactive.

At this time we simply do not know how dangerous or safe these newly created non-radioactive radiolytic products are.

In the February 14, 1984 *Federal Register*, FDA explains the differences between radioactive and radiolytic substances.

You should write FDA or your Congressman and ask for a free copy of this 9 page proposal.

FDA says: "Ionizing radiation, like other forms of energy used to process food, causes chemical changes in food. The chemical reaction does not involve the atomic nuclei of the food and, therefore, does not cause any radioactivity, but the reaction may produce molecules that are chemically distinct from those found normally in food."

These molecules are called radiolytic products.

It is important to emphasize again that although fresh food is irradiated at 10 million times the level used for a human X-ray, the food does *not* become measurably radioactive.

However, there are thousands of unanswered questions about the radiolytic products that *are* formed. But there are the same number of unanswered questions about all forms of food preservation. That doesn't mean all forms of preserving food are equally safe.

In good faith, FDA and Secretary Heckler have proposed that we approve more widespread use of irradiation as a method of decontamination which will reduce our dependence on treatment of food with such chemicals as ethelene dibromide (EDB).

We sincerely hope it turns out to be a step forward, not backward. To this end, we invite you to clip, sign and mail the enclosed form letter and get your friends to do likewise.

HEN

YES, WE'LL TAKE A RISK, BUT WE WANT A LABEL!

_____ 19_____

Margaret M. Heckler,
Secretary of Health and Human Services
and
Frank Young, M.D.
Commissioner of Food and Drugs
c/o Dockets Management Branch (HFA 305)
Food and Drug Administration, Rm. 4-61
5600 Fishers Lane
Rockville, MD 20857

Dear Secretary Heckler and Commissioner Novitch:

Thank you for your invitation to me, along with all other interested consumers, to offer comments and suggestions to improve FDA's proposal to greatly broaden the approved uses of irradiation of foods. (Federal Register, February 14, 1984; pp. 5714-5722)

I understand the new regulation would open the door for food processors to use irradiation instead of, or together with, highly toxic chemical pesticides and fumigants to destroy insects and extend the shelf life of fresh fruits and vegetables.

I also understand that irradiation of a food at the proposed levels does not make food radioactive. This, however, is NOT the basis of my safety concerns. I am concerned with other radiolytic changes that DO occur.

I do NOT agree with FDA's conclusion that simply because the food does not become radioactive it is therefore "safe" and has the identical nutritional value as similar foods which have not been irradiated.

Instead, I share the concern expressed by Dr. Samuel S. Epstein and John W. Gofman that "While not radioactive, irradiated food contains stable radiolytic products whose chemical identity and toxicology are poorly defined." *(The Washington Post,* February 25, 1984; p. A-16)

These newly formed radiolytic products may or may not be highly toxic. At this time we simply don't know.

Dr. Epstein and Dr. Gofman pointed out the FDA's assurance they are safe does not come from critical long-term feeding tests of concentrated extracts of these radiolytic products for mutagenic, carcinogenic and other chronic toxic effects.

FDA states in its proposal that "Ionizing radiation, like other forms of energy used to process food, causes chemical changes in food."

At the dosage proposed by FDA, irradiation of food "would produce approximately 30 parts per million of radiolytic products." Three parts per million or 10 percent of these may be entirely new substances that have never been tested for safety by any agency or any government. Thirty, or three parts per million, is an extremely high amount of very toxic poisons.

Doctors Epstein and Gofman said that "Industry claims for the safety of irradiated food largely depend on insensitive conventional animal feeding tests, rather than the more critical long-term feeding tests of concentrated extracts for carcinogenic and other chronic toxic effects." FDA should extend the comment time for nine months or more until at least one long-term feeding test of concentrated extracts of these newly discovered radiolytic products has been completed.

It is unfortunate, but true, that some food radiation safety tests contracted by the U.S. Army with Industrial Biotest of Northbrook, Illinois, were abrupty terminated when it was discovered the testing laboratory was falsifying their test results. While the guilty parties have been criminally prosecuted, the tests have never been completed or reinstated. Why?

The most disturbing aspect of FDA's proposal to allow increased irradiation of some of our foods is not the potential danger of the irradiated foods, no matter how great that may be, but in the unwarranted assurances by FDA and Secretary Margaret Heckler that the process is absolutely "safe."

Why not admit that we just don't know all the risks yet? We consumers can live with the fact that there is an unknown risk to new technologies. We are not dolts. We are risk takers. It goes with freedom.

Why not declare that irradiation of foods is the calculated risk it is, rather than issuing such misleading statements as "In fact, at the dosage levels we have established there is *no* residue from the treatment" and "Some education will be necessary, but once the public realizes that ionizing energy is just another form of energy—completely safe, leaving no residues—I am confident there will be widespread agreement on the need for this important technology." (Heckler's February 14 speech to the National Food Processors Association, NFAP)

I agree with NHF that it is wrong for FDA to paint itself into a corner by saying, long before the scientific evidence is in, that irradiation of foods is "COMPLETELY SAFE."

Even those with short memories can remember the same positive assurances of absolute safety given by FDA and other agencies that EDB, DDT, DES, and dozens of other pesticides, preservatives, food additives and drugs were "safe" only to later discover they were extremely toxic at or far below the levels approved by FDA. Each time this happens, consumer confidence in the integrity of our government is eroded a little.

WE'LL TAKE A RISK BUT WE WANT A LABEL.

I do not agree with the NFPA/FDA proposal that irradiated foods should not be labeled at the retail level because they are "safe."

Whether the process is dangerous, as its opponents fear it may be, or as safe as its proponents insist it is, those of us who knowingly want to take a risk (and there will be many) should be allowed to do so PROVIDED we are fully informed with a label that we are consuming food which has been irradiated.

I respectfully request that you extend the time for comments for an additional nine months. The 60 days in your proposal is not at all adequate for a proposal of this magnitude.

In summary, please (1) require a label, (2) extend the time for comments until at least one feeding test of concentrated extracts as proposed by Epstein and Gofman has been completed, and (3) don't prematurely assure us irradiated food is "completely safe."

Respectfully yours,

Signature _____ Print Name _____

Address _____ City _____

State _____ Zip Code _____

P.S. My fourth comment is that the records of irradiated food processors should not be destroyed after only one year following the shelf life of the fresh fruit or vegetable, as proposed by industry and FDA. Instead they should be kept for at least two generations so scientists can check for birth defects and other long-term possible injuries.

This form letter was prepared for my convenience by Clinton Ray Miller, Health Freedom Legislative Advocate of the National Health Federation, 5001 Seminary Rd., #1330, Alexandria, VA 22311. Phone: (703) 379-0589. Additional copies: $5.00/50; $9.00/100 at NHF, Box 688, Monrovia, CA 91016.

(B-102)

NATIONAL HEALTH FEDERATION NHF
CLINTON RAY MILLER
5001 Seminary Road, #1330,
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FOR IMMEDIATE RELEASE

November 13, 1984

IRRADIATED FOODS SHOULD BE LABELED

Clinton Ray Miller told the nation's leading promoters of food irradiation today that if it weren't for their incredible scientific arrogance and silly stubbornness in opposing a label, that thousands of health minded consumers would be clamoring to have the U.S. Food and Drug Administration (FDA) and the U.S. Congress change their archaic regulations and laws which outlaw irradiation of fresh fruits and vegetables.

Mr. Miller is the Health Freedom Legislative Advocate of the National Health Federation. He said NHF has successfully joined with industry in the past to amend federal laws to allow consumers to take major risks with their health and their lives.

"Health Freedom means the right to take risks," said Mr. Miller. "But give us a label to inform us of the risk we are taking."

"If a person doesn't have the right to be wrong, he or she is not free," he said.

"I personally believe that irradiated food may possibly be hazardous to health," Mr. Miller said. "I do not want to eat any irradiated food on a regular basis and will go to a great deal of inconvenience and expense to avoid it."

"However," he conceeded, "irradiation may be far less hazardous than most of the powerful fungicides and pesticides now approved by FDA as "safe" to keep fresh food from spoiling before it is consumed. At this point, we simply do not know."

"My personal beliefs are not at issue here," said Mr. Miller. "The issue is Health Freedom."

"I don't smoke or drink, but will defend to my death the rights of those who want to do so " he said.

"A label to inform consumers that a food being offered for sale has been irradiated would clear the way for immediate legalization of irradiated food," Mr. Miller insisted.

"The American Consumers are incredibly sophisticated, tolerant, and well informed," he said. "As such they do not believe the FDA or the food and drug industry when they give assurances that a new technology, drug, or pesticide has been discovered which is "completely safe." They've been through this before with DDT, DES, EDB, Asbestos, the Pill, the Dalcon Shield, Dioxin, Agent Orange, etc., etc., etc., etc., etc.

"Mr. Miller had high praise for Margaret Heckler, Secretary of Health and Human Services, but said her assurance that irradiatio. food was "completely safe" was taken as seriously by most people as Mondale's assurance that all the polls were wrong.

"It is this kind of talking down to the consumer by scientists and those in temporary positions of authority which builds the fires of resentment and rebellion," Mr. Miller said.

"Why not admit that we just don't know and put a label on the food so people can make an informed choice," he pleaded.

" If it takes several more years to get FDA and Congress to approve irradiation of food it will be the fault of arrogant pseudo scientists and overzealous bureaucrats who lose their credibility when they try to convince us that the evidence is all in, the subject is closed forever, and irradiation of food is "completely safe."

"American's are risk takers. They believe in health freedom and the risks that go with it. Since we are willing to take a risk, we want to be informed with a label," Mr. Miller said. "Is that too much to ask?"

Washington Post

WEDNESDAY, MARCH 20, 1985

E1

Safety, Risks & The FDA

Sanford A. Miller Believes In a Little Common Sense

Sometimes we wonder what's in the minds of our civil servants, those faceless bureaucrats who often affect our lives, but whom we know only as The Federal Government. Food section reporter Carole Sugarman talked to Sanford A. Miller, director of the Food and Drug Administration's Center for Food Safety and Applied Nutrition, which is responsible for overseeing the safety of the nation's food supply, ranging from regulation of food additives to food labels.

As its director, Miller is no ordinary federal employe. Both inside the agency and out, he is known as a connoisseur, a renaissance man and a colorful raconteur. He studies the dynamics of food, culture and cooking as much as the interactions of food, politics and science. At 53, Miller has been at the FDA since 1978. Prior to coming to the FDA, he was a professor of nutritional biochemistry at the Massachusetts Institute of Technology, where he is presently on leave.

—

Q *What would you do as a private citizen when it comes to food safety if you weren't in the government and if you didn't have a scientific background?*

A I think the first thing I'd do is make myself knowledgeable about the issues. And I mean not to accept without question any negative or critical reports that people are giving about the FDA. Look at the issues themselves.

You don't need a scientific background. All you need is common sense. If you think about it for a minute, there are some people who believe that if you find one sample that exceeds the tolerance for a pesticide, that's going to cause cancer when you eat it. And the fact of the matter is, the tolerances are set at a level which is not only safe but safe if you consume that level your entire lifetime. So that the fact that you have an occasional one that goes above it is meaningless.

All right, so you get a report from an organization that says, "Ah ha, we found traces of this pesticide in food. Why isn't the FDA doing its job?" It doesn't take much common sense to realize that of course you're going to find traces of pesticide in occasional products. The more important thing is what is the pattern over a period of time.

Q *But how do you determine how safe is safe enough?*

A That of course is the big debate. What you have to come to is the basic understanding that nothing is without risk. There isn't anything in this world, including me talking on the phone to you right now, as you well know, that's without risk. Even the most pleasurable thing in the world—ranging from sex to watching a good movie, or eating—is not without its risk.

What you have to do is try to get some handle on the relative risks that might be involved. Most of us deal with a kind of intuitive perceptual risk, which isn't very useful because we tend to overestimate the risks of the things we don't know about and underestimate the risks we're familiar with. But if I told you that the chances of anything, anything in food causing your death—even accumulation over a lifetime—was fractional compared to the risks of driving your automobile, you wouldn't buy that. But yet that's a fact.

Q *But doesn't part of it have to do with who's in control?*

A You know, there's a thing in America which is one of things which makes us, frankly I think, such a great democracy. We don't trust government. By definition, government, at very best, is a friendly adversary. Most of us come from backgrounds from other countries, where government was once a more active enemy. And so this whole country was founded by people who distrusted government. The result of this is that that same philosophy still exists today. People simply refuse [to believe] that the government is trying to do something on their side, irrespective of what it does.

Q *Do you think there is any way to change that, or is that just the way it should be?*

A That's where we are, and I think the regulatory agencies accept that. I think what we don't accept is somehow the idea that somehow or other what we do is the result of chicanery or dishonesty or of being bought by somebody. There's no decision that this bureau can make that is not controversial and which people like. We are accused as often as being on the side of industry as we are of being controlled by the consumer people. Each one thinks we're in the

See MILLER, E10, Col. 1

MILLER, From E1

pocket of the other. If you look at our record, we've approved some things that the consumers don't want us to approve, we don't regulate some things that the industry wants us to regulate and we just do whatever we think is the most objective way of handling it. But the end result of all this is constant criticism, constant beating on the head, which after a while wears people out. What happens is that we lose good people and find it very difficult to get good people to come into this kind of environment.

Q *So, you being in that position, why do you do it?*

A Remember, I came into it late in life. I spent 20 some-odd years teaching in a university and among the things I tried to get across to my students is that as teachers at a university and as scientists, among other things, we had not only a personal responsibility or an abstract responsibility to something called increasing knowledge, but a responsibility to the public.

When I was asked to come down here by Don Kennedy [then FDA commissioner] in 1978, my students then turned to me and said, "Now put up or shut up." And they were right. I told them I would come and I came for two years. I've been here for six. It is a man-killing or a woman-killing job to every day have to make a decision which you know conceivably is going to effect the health of 240 million people. And this wears on you for awhile and so people in this job don't last very long. I do not expect to retire in this job.

Q *How does it [your job] make you feel from day to day? Is it pressure, is it frustration, is it stress? What is it?*

A It's everything. It's pressure, frustration, stress, worry, concern. Because, remember, the easiest thing to do is to say "no" to everything. But if we said that, then we might as well close up shop and we'd all die of starvation. I mean, let's face it, you can't grow the food you need, or run steers or grow fish on the 30th floor of a condominium. Therefore you need a food industry.

Q *What foods do you avoid?*

A Oh, I don't think there's very much. At home, we tend to eat a varied diet within limitations of a very busy family. I think we try to reduce our fat intake and there are lots of reasons for that. But there are very, very few foods that we will not eat. We don't eat a heck of a lot of candy bars, but that's just moderation. That's not to say we don't eat them.

Q *How many cups of coffee do you drink a day?*

A I drink a fair amount, maybe six or seven cups of coffee a day, but then I'm not pregnant or an adolescent. On the other hand, my daughters I've talked into keeping some restriction on their intake to less than four cups a day.

Q *How about soft drinks?*

A We drink soft drinks. Again, not a heck of a lot. I suppose when I'm on a diet, I drink more than when I'm not.

E10 WEDNESDAY, MARCH 20, 1985 THE WASHINGTON POST

Safety & Risks

Q *Are you on a diet?*

A Almost always.

Q *Is it hard to practice what you preach?*

A Oh sure, of course. That's the reality of life. It's very hard to deal with those kinds of issues, unless you start out with them as a very young child. We're the products of our parents, and for most cases, it can be useful. From the kind of background I come from it didn't help me a hell of a lot in terms of weight control.

Q *What do you think the American public misunderstands the most when it comes to the FDA's role in food regulation?*

A I think they believe we have a lot more power than we do. And they believe we can act by fiat, which we don't. Everything we do has to be operated in the openness of public participation. Every regulation we do has to be noted and commented. We are constantly under surveillance, not only by Congress, but the courts and the newspapers and everybody else. Every action we take is examined with a fine magnifying glass. That just takes longer. That means that the process is very slow. We must have all of our chips in order to take any action. We must be prepared to deal with litigation on every issue, criticism from the press on every issue, and the result is that it takes one hell of a long time.

Now people say, "why does it take you so long to act?" The choice they have to make is, do they want an open participatory kind of regulation or do they want the kind that virtually every other country in the world has? Regulators operate by fiat, you have no recourse.

Q *How about regulatory action on restricting the use of sulfites? Why hasn't the FDA done anything about that?*

A The fact is that we did. If you've been through the problem that we faced with that, you'd realize that the problem had to do with a segment of the population. The bulk of the population by far has no problem with sulfites.

The fact of the matter is, there are literally hundreds if not thousands of substances to which people are exposed to, and indeed every year there are people who die, many people who die because they are exposed to something to which they're sensitive to.

Q *Do you think that sulfites should not be banned?*

A No, let me get try to finish the point. Traditionally, our way to approach the problem is through labeling. People read a label and see it's there. The problem with sulfites is that in most situations it's applied as an aerosol in a restaurant situation. That's the place where labeling is probably least effective. Having said all that, you also have to understand that we don't control restaurants. The state controls them. Our approach was get the states to do the job here because that's who he they operate. We don't have authority or people to do this work. And that's been overly since '82. So we've tried several other things going on more local activities. We've put together a proposal concerning labeling, which is now being reviewed, and there are some other proposals as well, but those take a long time as I've told you.

Q *Do you think irradiated foods should be labeled?*

A Yes, I personally do. The department may have another view on this, and there actually are some good reasons why you shouldn't have to do it. Why should you have to label irradiated foods when you don't have to label heat-processed foods or frozen foods? My own feelings are that it should be labeled, and when it's all said and done, I think it will be.

Q *What do you think is the major nutritional problem of the American public? What FDA policies are being or should be adopted that could address those issues?*

A I think obesity is, without question. But I think the other part of it is that the main nutrition problem with the American public is the lack of information. I think that our attempts to provide information in several different forms, plus working with Giant supermarket with shelf labeling and working with the department on educational things, will correct that with time. And people will be able to make appropriate decisions, so that this dietary pattern concept—that certain diseases such as cancers or coronary heart disease is a function of a pattern of the diet, not any particular thing in the diet—could be exploited so that people will have enough information to make appropriate dietary choices.

There's another point here. One of the important things that needs to be done—and will be done in the next five to 10 years—is that we've got to link agricultural policy and nutrition policy and health policy in this country. And I think that's coming. That means that farmers will be rewarded, not on the basis of just producing product, but by producing products that have certain health characteristics.

SANFORD A. MILLER

Q *About the health claims issue. I know that the FDA has been cautious on its policy about health claims on food labels and that the FTC has applauded health claims on advertisements such as the recent ad Heinz did that claims ketchup could help prevent cancer. What do you think of the FTC's policy?*

A I don't want to comment on the FTC's policy, except to say one thing. Often what appears to be fundamental differences between agencies is really differences in the laws, differences in the dimensions of the laws, the limits of the laws, and differences in the kind of things we regulate. We're concerned with the label itself. There, there's a tight connection between what people believe of an industrial product and the message on it.

Q *You don't think people make that connection in an ad?*

A The ad can be written in such a way that doesn't necessarily make it [the connection]. Plus, our law requires us to be very, very rigorous in our review of the data under which a claim is made. FTC's law doesn't read that way. They're susceptible to litigation if they try to be rigorous in that regard. I don't think there's a real conflict here.

Q *Do you think that FDA's voluntary sodium labeling program has been adequate, given the fact that only 50 percent of foods contain such labeling?*

A Sure, what it means is that virtually every product category has some foods that are sodium labeled.

Q *So how do people use that?*

A To compare one product to the other. If the data isn't there, then I think it's up to the public to say, 'Okey, I'm not going to buy it.' The public has got to play a role in this. We've got to get out of this business of the public as a passive component of the process. Irrespective of regulations, the public has got to express what they want in an active way by not buying products that aren't sodium labeled.

EXHIBIT # 6

USA TODAY • FRIDAY, NOVEMBER 1, 1985 • 9A

WHERE TO PUT IT

RADIOACTIVE RESIDUE

Nuclear legacy

Decisions near on where to bury deadly waste

By Marilyn Adams
USA TODAY

Potentially explosive decisions on where the USA will put its most dangerous nuclear waste are coming soon.

By early next year, the U.S. Department of Energy will pick three potential sites — possibly in Washington, Texas and Nevada — from nine.

Each will get $1 billion in tests to see if it's safe for burying high-level radioactive waste for 10,000 years.

By year's end, the government will narrow a list of 235 potential sites in 17 states to 15 sites in up to six states for a second waste area to open in 2006.

"We have the data and confidence to choose the right method," said Energy Department official Ben Rusche.

Industry experts agree. "The problem ... is political. We have this 'Not in *my* backyard' syndrome," said the American Nuclear Society's Lynn Wallis.

But the Environmental Policy Institute's David Berick said "lawsuits will start in earnest" when the lists come out. Nine suits already have been filed.

Critics say the government rushed under a tight schedule. Nuclear Regulatory Commissioner James Asselstine thinks the program may be in jeopardy. "Now is the time to make sure we're on the right course. When you have everyone talking about lawsuits this early ... it's a blueprint for trouble."

The issue is most immediate in the West, where the first waste area would open in 1998. Criticism of the three preferred sites has prompted the Energy Department to ask the National Academy of Sciences to check the selection method:

■ At Washington's Hanford site, local people want the facility, but it would be near the Columbia River.

■ Vibrations might affect the Nevada site, near the nuclear weapons test site.

■ The Texas site is a major farm area and part of an underground water reservoir spanning eight states.

Battle rages with lawsuits, ads

Environmentalists are joining hunters, fishermen and farmers to fight a nuclear waste "dump," while utilities buy ads saying it's safe.

Eight environmental groups and 10 states have filed nine lawsuits. Interest groups lobby intensely over where to bury high-level nuclear waste:

■ **Northern States Power Co., with customers in Minnesota, Wisconsin and Michigan, will buy ads this month to calm customers' fears.**

■ **City officials and businessmen near the Hanford, Wash., site passed resolutions favoring the waste area because it would create jobs.**

■ **Minnesota Public Interest Research Group, which opposes the program, met with labor, church and farm clubs and went on talk shows.**

■ **State scientists analyzed New Hampshire using federal criteria, assuring residents their state won't be picked.**

■ **Vermont legislators wrote to counterparts in 16 states urging more concern.**

Federal officials have toured the USA to explain the complex program, often meeting hostile audiences. Hearings in Vermont attracted up to 2,000, including busloads of Canadians.

— Marilyn Adams

Testimony

of

Dr. William W. Marion
Executive Vice President
Council for Agricultural Science and Technology
Co-chair, Institute of Food Technologists
Committee on Research

Congressman Bedell and distinguished members of the subcommittee:

I am William Marion, Executive Vice President of CAST, which is the Council for Agricultural Science and Technology. CAST has its office at 137 Lynn Avenue, Ames, IA. In addition, I serve as co-chair of the research committee of the Institute of Food Technologists (IFT), a scientific society representing 26,000 food scientists and technologists in academia, government and industry.

CAST is a national organization of 25 (soon to be 26) scientific societies in food and agriculture. It is controlled by these societies through their representatives on the board of directors. It derives its financial support from these societies, its sustaining members, and some five thousand individual members.

CAST produces scientific, educational publications on current food and agricultural issues of national importance, mostly by means of multi-disciplinary task forces of scientists who are nominated by their respective scientific societies. It also publishes "NEWS from CAST" six times annually. This document presents information on major issues in brief form. In addition, CAST publishes an educational magazine, "Science of Food and Agriculture," that is sent free of charge to heads of science departments in high school grades 9 through 12 nationwide. Undoubtedly, you are familiar with one or more of the publications.

Thank you for the invitation to appear before you today and to comment on HR 696, the Federal Food Irradiation Development and Control Act of 1985. Both CAST and IFT have published documents in this field of food processing previously. CAST presently has a major task force effort underway on the topic of irradiation. The first of two publications, "Wholesomeness of Food Treated with Ionizing Energy" has been written and is in the review process.

It should be published by about the end of this year. A second paper on "Applications" will be published sometime in 1986. Dr. Brynjolfsson is a member of that task force.

It has been said that there have been no totally new food processing techniques developed in the twentieth century. Many refinements in the long-established processes of canning, drying, freezing, curing and fermenting have been made. And the use of microwave energy of course, has become common in home cookery. The use of ionizing radiation can become an option for a "new" food processing technique.

Low-level irradiation of food offers several advantages. It will greatly extend the shelf-life of perishable foods such as strawberries. Pork, which contributes significantly to the nutrition of most Americans, is sometimes viewed with suspicion by consumers who fear trichina infection. The incidence of trichinosis infection in humans is very low indeed (30 cases in 1983; 95 in 1982). Nevertheless, the U.S. Department of Agriculture and other advisory groups correctly point out that pork should be cooked to a well-done stage. That implies internal temperatures of 165 to 170°F. Actually, trichina are inactivated at much lower temperatures (138 to 145°F), but in choosing to be safe consumers eliminate the use of pork in a number of traditional European recipes. The use of irradiation to inactivate the few trichina that may be present could have a positive effect on pork consumption, with a commensurate positive economic effect on the surplus grain supply. Likewise, increased processing and marketing activities associated with the pork industry should follow.

Mr. Chairman, this concludes my general remarks. It is now my pleasure to present Dr. Ari Brynjolfsson, a physicist from Natick Laboratories, Natick, MA.

REVISED

Ari Brynjolfsson Nov. 18, 1985

STATEMENT OF DR. ARI BRYNJOLFSSON, MEMBER OF THE SCIENTIFIC TASK FORCE ON WHOLESOMENESS OF FOODS TREATED WITH IONIZING ENERGY, ORGANIZED BY THE COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY, 18th OF NOVEMBER, 1985

1. INTRODUCTION

My name is Ari Brynjolfsson. From 1972 to 1980, I was director of the United States National Food Irradiation Program, conducted by the U. S. Department of Army at the Natick Laboratories in Massachusetts. I was chairman of the Codex Alimentarius Committee on Food Additive's Working Group that developed the "Codex Alimentarius General Standard for Irradiated Foods", and "Recommended International Code of Practice for the Operation of Facilities Used for Treatment of Foods"; and I was technical Advisor to the Joint IAEA/FAO/WHO Expert Committee on Wholesomeness on Irradiated Foods. Today, I am appearing before your Subcommittee on Department Operations, Research, and Foreign Agriculture in my capacity as a member of the Scientific Task Force on Wholesomeness of Foods Treated with Ionizing Energy, organized by the Council for Agricultural Science and Technology.

A list of Task Force Members is attached as enclosure 1 with this statement. I am also enclosing two articles closely related to the subject [A. Brynjolfsson; Wholesomeness of Irradiated Foods: A Review. Journal of Food Safety, 7 , (1985) pp.107-126; and A. Brynjolfsson. Food Irradiation in the United States, Proceedings of the 26th European Meeting of Meat Research Workers at Colorado Springs in 1980, Volume 1, pp. 172-177]

I will give you a preview of the major findings in the first part of the Task Force report which deals with: Wholesomeness of Food Treated with Ionizing Energy. This part which is not in its final form but has gone through the first edition and review by all the members consists of four main sections: 1.) "Radiolytic Products" prepared by Dr. Charles Merritt, Jr., who with Dr. Irwin Taub was one of the key individuals coordinating the analytical chemistry work on irradiated foods at Natick Laboratories MA; 2.) "Toxicological Aspects" prepared by Dr. Julius M. Coon, Department of Pharmacology, Thomas Jefferson University, Philadelphia, PA. and Dr. Edward S. Josephson, Senior Lecturer at MIT and former director (1961-1972) of the U.S. Food Irradiation Program at Natick MA, and co-chairman of the Task Force; 3.) "Nutritional Aspects" prepared by Dr. Edward S. Josephson; 4.) "Microbiological Safety" prepared by professor R. Burt Maxcy, Department of Food Science and Technology, University of Nebraska, and Dr. Eugen Wierbicki, Eastern Regional Research Center, U. S. Department of Agriculture, Philadelphia PA.; and 5.) "Induced Radioactivity" prepared by Dr. A. Brynjolfsson. The work was coordinated by the Chairman of the Task Force, Dr. Eugen Wierbicki, who also obtained many of the foreign reports on the wholesomeness evaluation of irradiated foods.

Ari Brynjolfsson Nov. 18, 1985

2. MAJOR FINDINGS IN THE TASK FORCE REPORT

The report is now undergoing final editing for submission to the printer. I can state for the record that in reviewing the voluminous scientific literature on the subject, the members have found nothing to indicate that irradiated foods are not wholesome when treated up to an average radiation dose of 58 kilograys with ionizing radiation from cobalt-60 or with 10 MeV electrons.

A priori, it was to be expected that some of the results in these extensive experiments would indicate a possibility of detrimental effects, because when the animals on the irradiated test diet do better than those on the control diet it is assumed that the detrimental effect appearing in the control diet is due to statistical fluctuations, but when the detrimental effect appears in the test diet it makes the test diet suspect. Subsequent analysis as well as other experiments have as a rule shown that the detrimental effects were due to statistical fluctuations or faulty experiments.
The major findings of the analysis were as follows:

A) It appears proven with reasonable certainty that foods irradiated with doses up to an average dose of 58 kilogray are safe and wholesome.
This conclusion is based on two principally different approches:
a) the analyses and toxicological evaluation of the radiolytic products; and
b) the evaluation of the results from extensive animal feeding studies.

B) The effect of irradiation on the nutrition are either insignificant or comparable with other currently accepted food treatments.

C) The irradiation does not introduce any special microbiological problem.

D) No induced radioactivity is produced in the food when the proposed sources are used.

From these findings, we may conclude that:

The process of preserving food by irradiation up to an average dose of 58 ilogray accordingly should be recognized as safe and wholesome.

Irradiation, like other processes for preserving the food for public consumption, requires adherence to high hygienic standards and sound principles in processing, storing, and distribution of the food. FDA and/or USDA should accordingly inspect and approve of the irradiation facilities for processing and control of the foods; and as they do in other federally inspected plants, keep surveillance to assure adherence to good manufacturing principles for the benefit of the consumer. Present standards and regulations for treatment of nonirradiated foods, such as standard hygienic manufacturing

practices, can be applied and expanded to irradiated foods. The Codex Alimentarius "International General Standard for Irradiated Foods" in international trade form a reasonable framework for regulating the process not only for international trade but also for trade within the country. (Codex Alimentarius Commission, 1984) These standards could with simple modifications be applied to foods treated with sterilizing doses. Likewise, the Codex "International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods" forms a framework and provides guidelines for operating the irradiation plants for processing of foods.

3. THE ANALYSES OF THE RADIOLYTIC PRODUCTS IN THE U.S.A.

Extensive chemical analyses have failed to discern any chemicals that are not found in some nonirradiated foods or in foods subject to other accepted processes, such as cooking. From the composition of the food, the irradiation dose, and the irradiation conditions, it is possible to predict the general nature and the approximate yields of radiolytic products formed. A given food component, such as a fat, produces the same kinds of radiolytic products independently of the food in which it occurs. The amount of radiolytic products produced from a component such as linoleic acid is roughly proportional to the amount of linoleic acid in the food. If there is six times more linoleic acid in poultry meat than in beef, then there will be six times as much heptadecadiene, which is derived from linoleic acid, produced in poultry meat than in beef when they are irradiated. The amounts of the different radiolytic products are in most cases approximately proportional to the dose.
It is therefore not necessary to examine as a separate case each food to be irradiated.

4. TOXICOLOGICAL EVALUATION IN THE U.S.A. OF THE RADIOLYTIC PRODUCTS

In the U.S., the analyses of the radiolytic products formed in the meats, that were irradiated with an average dose of 58 kilogray, were evaluated by a "Select Committee on Health Aspects of Irradiated Beef", under the auspices of the "Life Sciences Research Office, Federation of American Societies for Experimental Biology". This Committee concluded after evaluation of the volatile compounds in beef that (F.A.S.E.B. 1977):

> "On the basis of the available data, the Committee concluded that there were no grounds to suspect that the radiolytic compounds evaluated in this report would constitute any hazard to the health to persons consuming reasonable quantities of beef irradiated in the described manner."

In 1979, the Committee evaluated other compounds measured or deduced from reactions schemes and model systems and concluded that in meats that were irradiated with an average dose up to 58 kilogray (F.A.S.E.B. 1979a, and 1979b):

"No evidence is available which indicates a toxicity of any of these compounds at the concentrations anticipated in irradiated beef, although in some cases, inadequate information is available to permit a firm judgement at this time on their possible health effects."

Subsequent analyses of the radiolytic products from other meats in addition to beef have failed to turn up any product that is not commonly found in nonprocessed and processed foods.

5. ANALYSES OF THE RADIOLYTIC PRODUCTS ABROAD

Analyses of many other food products were carried out in other countries. In 1978, the International Project in the Field of Food Irradiation (IFIP) set up a Coordinated Program on the Radiation Chemistry of Food and Food Components (CORC). The various laboratories collaborating in the research studies on radiolyses products prepared a series of working papers which were submitted to the 1980 Joint WHO/IAEA/FAO Expert Committee on the Wholesomeness of Irradiated Food,(JECFI.) [The International Project in the Field of Food Irradiation with 24 member countries including USA and sponsored by the Food and Agricultural Organization (FAO) and International Atomic Energy Agency (IAEA) of the United Nations, as well as the Nuclear Energy Agency of the Organization for Economic Cooperation and Development (OECD/NEA), with the World Health Organization in advisory capacity.]

6. TOXICOLOGICAL EVALUATION OF THE RADIOLYTIC PRODUCTS BY JECFI

The data and the theoretical analyses [Elias and Cohen, Eds. 1983] were submitted to JECFI. The data provided the evidence that the formation of the radiolytic products was predictable, and the data obtained from the investigations of the many foods could be extrapolated and interpolated from one food to another. These findings together with the toxicological evaluation of the radiolytic products, as well as the evaluation of the many animal feeding experiments formed the basis for the recommendation by JECFI that irradiated foods are safe and wholesome. [JECFI, 1981]

7. THE ANIMAL FEEDING STUDIES.

During the last 37 years, the effect of irradiation on the wholesomeness of food has been studied more thoroughly than that of any other processing of foods. Already in 1965, the Office of the Surgeon General of the U.S.Army, who had sponsored extensive studies in the fifties and early sixties, concluded that [The Surgeon General of the Army, 1965]:

"Foods irradiated up to absorbed doses of 5.6 megarads (= 56 kilogray) with a cobalt 60 source of gamma radiation or with electrons with energies up to 10 million electron volts have been found to be wholesome, i.e., safe and nutritionally adequate."

In 1980, the JECFI was able to expand significantly the 1976 recommendations [JECFI, 1976] and after extensive review of the data collected up to Oct.1980 [Anon. 1985] concluded [JECFI, 1981]:

> "... that the irradiation of any food commodity up to an overall average dose of 10 kilogray presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required."

JECFI had available much information about studies on foods irradiated with sterilizing doses; but JECFI limited its conclusion to foods treated with doses less than 10 kilogray, because two important studies on foods irradiated with higher doses were still being conducted. In particular, the animal feeding studies on irradiation sterilized chicken conducted by Ralston Purina Company for the Office of the Surgeon General of the U.S.Army, and later continued by U. S. Department of Agriculture, had not been completed by November 3, 1980, the date JECFI ended its meeting and announced its conclusion. Nor had the evaluation been completed of some very thorough studies in The Netherlands on meats irradiated at high doses.

> The extremely thorough and extensive longterm multigeneration animal feeding studies, including several mutagenesis tests and teratogenesis tests, as well as several antivitamin studies have now been concluded, without any discernible harmful or detrimental effects of irradiation on the food. [Tracor Jitco, Inc. 1983; Anon. 1985; and Brynjolfsson, 1985]

Further,

> In The Netherlands, a series of very thorough studies have been completed on irradiation sterilized pork and feed, without any discernible harmful or detrimental effects of irradiation on the food. [van Logten et al. 1983, 1980 and 1978]

8. THE NUTRITIONAL QUALITY.

Irradiation is most effective in inactivating the huge macromolecules of a living organism, such as DNA, which are essential for its survival. This accounts for the fact that radiation as a rule is very harmful to living organisms. The smaller molecules of food are less affected. Even many enzymes, which actually are very large molecules although not as large as the DNA, are not much damaged, especially when dry or frozen. This accounts for industrial use of irradiation for sterilizing the dry enzymes. The large molecules, such as the DNA, the enzymes and the proteins are digested or hydrolyzed into the smaller basic units of food before they enter our blood and lymphatic system. The basic units of the major nutrients in the food, such as the amino acids of the proteins, the fatty acids and the monosaccharides are much smaller molecules than the enzymes and the DNA and are therefore largely intact after irradiation even with the highest doses. Less than about 1% is damaged when the food is sterilized. This is much smaller than the measuring sensitivity in any protein efficiency study.

This very small damage to the food when it is irradiated accounts for some of the limitation of irradiation. Enzymes which are intact after irradiation may gradually break down the texture of the food. Sometimes, this gives an advantage to the process. It may facilitate the aging of meat by softening the texture of tough meat. At other times, it may prevent long term storage because the meat would get too soft or mushy.

Foods that are to be stored for extended time without refrigeration will have to be enzyme inactivated before irradiation. Usually the foods have been enzyme inactivated using mild heat treatment, in the range of 70 to 90 °C (158 to 194 °F) depending on the product.

There are exceptions to the main rule that the irradiation does not affect significantly the nutritional components of the food. In case of some of the micro-nutrients such as thiamine (vitamin B_1), the losses at sterilizing doses, 50 kilogray, may be significant. Thiamine is very reactive towards many of the radiolytic products and acts as a scavenger for them, especially when the thiamine is in the water phase of the food. The destruction of this vitamin, when the food is irradiated at room temperature, is about the same at high doses as in the thermal processing. At the low doses used for disinfestation of fresh produce, or for elimination of trichinosis, the damage is much smaller and insignificant. At sterilizing doses the damage to the vitamins is reduced by irradiating the food in vacuum, and in frozen or dry state.

On the subject of nutrition JECFI concluded [JECFI, 1980]:

> "Evidence from most studies suggests that in the low-dose range (up to 1 kilogray) used for the irradiation of food, nutrient losses are insignificant. In the medium-dose range (1-10 kilogray), losses of some vitamins may occur, if air is not excluded during irradiation and storage. In the high-dose range (10-50 kilogray), the technology used to avoid effects on organoleptic quality (i.e., irradiation at temperatures below freezing and in the absence of air) also partially protects nutrients, so that losses may actually be lower than in the medium-dose range if such precautions have not been taken."

As a guideline we thus have that the effect of irradiation on the nutrients are either insignificant or comparable with other currently accepted food treatments.

9. MICROBIAL SAFETY.

The microbiological safety of irradiated food is fully comparable with that of food processed by currently accepted methods. In all cases it involves adherence to good manufacturing practices, including high hygienic standards throughout the processing and storage before, during and after processing. It involves consideration of the possible contaminating flora, knowledge about the preprocessing levels, determination of the inactivation factors, and proper storage temperatures for preventing outgrowth.

During the animal feeding studies of beef, pork, ham and chicken meat, about 240 tons were sterilized by radiation, and the irradiated foods were kept up to 24 months at room temperature. No incidences of non sterile product was encountered. A sterilizing dose is determined for each product as that which reduces the number ofspores of Clostridium botulinum from 10^{12} to 1, and is usually in the range from 25 to 45 kilogray.

Often the products can be made safer and their shelf life extended by use of substerilizing doses, usually in the range of 0.5 to 5 kilograys, combined with refrigeration during storage. This dose range will reduce, or eliminate disease-causing organisms, such as: salmonellas, shigellas, coliform bacterias, staphylococci, streptococci, brucellas, vibrospecies, Yersinia enterocolitica, Campylobacter jejuni, and Aeromonas hydrophilia. Doses above 0.15 kilogray will sterilize the food borne helminth Trichinella spiralis, and thereby prevent the disease trichinosis. Other helminths and parasites such as Toxoplasma gondii, which is inactivated by 0.1 to 0.3 kilogray, are similarly eliminated with low doses of radiation.

Sometimes, the question is raised about the possibility of producing new and harmful microbial mutants. At the request of FAO and WHO, the subject was considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiological Societies on 16 December, 1982. The Board met at the Royal Veterinary and Agricultural University in Copenhagen and concluded. [Anon. 1982]

> After analyzing the scientific knowledge available to date, the Board was satisfied that there was no cause for concern and that modern techniques were adequate to control the situation. Food irradiation was considered to be an important addition to the methods of control of foodborne pathogens and not to present any additional hazards from shifts in the microflora or changes in the attributes of the microorganisms.

The underlying reasons explaining the experimental observations leading to this conclusion are delineated in an article by Brynjolfsson [1985]

10. THE INDUCED RADIOACTIVITY.

> No measureable induced radioactivity is produced when the foods are treated with gamma-rays from cobalt-60 or cesium-137, x-rays below 5 MeV, or electrons of 10 MeV or less.

This has been determined from measurements on foods treated with a dose of 58 kilogray of radiation from cobalt-60 gamma rays and 10 MeV electrons. The experiments showed that the induced radioactivity had to be less than the sensitivity in these measurements which was about 0.1% of the natural activity in the food. These measurements were extremely sensitive as the natural activity in the food varies significantly, often by factor of two, from one food to another and from place to place.

Theoretical estimates indicate that the activity is even much less than this experimental limit. For example, the isomeric activities produced by cobalt-60

would be more than million times smaller than the natural activity in the food, and irradiation with 10 MeV electrons would produce activity more than million times smaller than the natural activity in the food, and thus of no significance whatsoever.

11. WHY FOOD IRRADIATION

Irradiation is not a panacea for preservation of food or for extending its shelf life. It has its limitation, for example, it does not inactivate enzymes in the food that may decompose it; it will not prevent recontamination with microbes and insects; it does not prevent oxidation. Still, it may be useful for improving the quality of the food, for reducing the number of harmful pathogens, parasites and insects, for extending the storage life, and, thus, for providing the best food to the consumer.

A few examples will illustrate the point. Let us consider a need to sterilize dried, powdered and packaged onions. The alternative to irradiation is usually fumigation with ethylene oxide. Before fumigation, the product must be rehydrated by steam, preferably for 24 hours. The product is then exposed to the ethylene oxide for about 16 hours, flushed with air to drive out the toxic ethylene oxide and for drying the product. The powdered onions will now have clumped together and must be reground.

Similar procedures are involved in sterilizing many other food ingredients, spices and condiments. The process is involved because the process is not very effective unless the product is moist. It is important to drive off any residual ethylene oxide as it is toxic; much precaution must be taken to assure that the workers are not exposed to the gas and that the environment is not contaminated.

Apart from the heavier shielding around the sources, irradiation is applied to the product in a similar way that our luggage is x-rayed at the airport. Neither steaming nor repacking is required.

Another example may be enzymes used in the food industry. Often a heat sterilization would destroy the activity. On the other hand, sterilization or pasteurization of dry enzymes can often be made without much damage to the enzymes.

The astronauts may not be able to rely on refrigeration, and the heat sterilized food may seem dull and flat after few days on such diet; and they might enjoy for a change to get irradiated foods. The mountain climber, the farmer out in the field, the seaman out on his fishing boat may feel like the astronauts who after their historic flight to the moon reported about the irradiated foods that they had with them in space: "The juicy, chewy irradiated ham and cheese on irradiated rye was one of the space culinary delights enjoyed by the Apollo 17 astronauts".

There are people in hospitals who need sterilized diets. There have been indications from Fred Hutchinson Cancer Research Center, Seattle, Washington that some of the patients would prefer irradiated diets once in a while over their heat sterilized counterparts.

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12. USE OF ENERGY

The overall energy used in the irradiation process tends to be less than in many other processes. [Brynjolfsson, 1978] The use of the process will also tend to reduce the food losses. Therefore,

> the irradiation process will tend to reduce the overall energy used in the food industry.

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ARI BRYNJOLFSSON

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Ari Brynjolfsson ORAL PRESENTATION Nov. 18, 1985

STATEMENT OF DR. ARI BRYNJOLFSSON, MEMBER OF THE SCIENTIFIC TASK FORCE ON WHOLESOMENESS OF FOODS TREATED WITH IONIZING ENERGY, ORGANIZED BY THE COUNCIL FOR AGRICULTURAL SCIENCE AND TECHNOLOGY, 18th OF NOVEMBER, 1985

My name is Ari Brynjolfsson. From 1972 to 1980, I was director of the United States National Food Irradiation Program, conducted by the U. S. Department of Army at the Natick Laboratories in Massachusetts.

Mr. Chairman, I appreciate to have the opportunity to present to the Committee the findings of the Scientific Task Force on Wholesomeness of Foods Treated with Ionizing Energy, organized by the CAST.

A list of Task Force Members is attached as enclosure "A" with this statement.

With me, I have the full text of the statement which I hereby submit for the record. It is 10 pages long, and I will therefore abstract it in my oral presentation. I also have with me articles and reports that are highly pertinent to the subject which I would like therefore to submit with my statement as enclosures "B" through "H".

MAJOR FINDINGS IN THE TASK FORCE REPORT

The major findings of the analysis were as follows:

I. It appears proven with reasonable certainty that foods irradiated with doses up to an average dose of 58 kilogray are safe and wholesome. This conclusion is based on two principally different approches:

   a) the analyses and toxicological evaluation of the radiolytic products; and

   b) the evaluation of the results from extensive animal feeding studies.

II. The effect of irradiation on nutrition are either insignificant or comparable with other currently accepted food treatments.

III. The irradiation does not introduce any special microbiological problem.

IV. No induced radioactivity is produced in the food when the proposed sources are used.

From these findings, we conclude that:

The process of preserving food by irradiation up to an average dose of 58 kilogray accordingly should be recognized as safe and wholesome.

Irradiation, like other processes for preserving food for public consumption, requires adherence to high hygienic standards and sound principles in processing, storing, and distribution. Present standards and regulations for treatment of nonirradiated foods, such as standard hygienic manufacturing practices, can be expanded and also applied to irradiated foods.

FDA and/or USDA should accordingly inspect and approve the irradiation facilities for processing and control of the foods; and as in other federally inspected plants, keep surveillance to assure adherence to good manufacturing principles for the benefit of the consumer.

FDA and USDA should be permitted to set more stringent standards for the design and operation of radiation facilities for processing of food than those that NRC has set for design and operation of radiation facilities used for processing of non-food items.

The Codex Alimentarius "International General Standard for Irradiated Foods" in international trade forms a reasonable framework for regulating the process not only for international trade but also for trade within the country (Codex Alimentarius Commission, 1984). These standards could with simple modifications be applied to foods treated with sterilizing doses. Likewise, the Codex "International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods" forms a framework and provides guidelines for operating the irradiation plants for processing of foods.

Mr. Chairman, members of this Subcommittee, I believe the Bill, H.R.696, will be very usefull as it is. I would like to make suggestion for minor correction or changes.

Under the heading: "FINDINGS AND PURPOSES" on page 2, we have in the paragraph Sec. 2(a)(2), the words: "and eliminates trichinosis in pork,". Humans get trichinosis from eating trichina, Trichinella spiralis in meats. I believe the sentence should be changed to "it eliminates trichinas in meat products," or as I would prefer: "it eliminates parasites such as Toxoplasma gondii and helminths such as Trichinella spiralis in meats,". Toxoplasma gondii is a parasite (protozoan) in raw meats. About 25% of the U.S. adults have antibodies indicating previous infection. While the disease in adults often has no noticeable symptoms, it may in a pregnant woman cause grave threat of birth defects in her child, including heart and brain damage and mental retardation. Toxoplasma gondii is eliminated by very low doses, less than 0.3 kGy, of radiation.

Under the heading: "LEASING OF NUCLEAR BYPRODUCT MATERIAL FOR FOOD" on page 10, I would like to see clearer support for research and development. I believe the consumer, the industry, and the nation would be best served if university and industry laboratories were encouraged to continue to research and develop the technology and to educate and train the food technologists, and thus assure the best product. I believe that if the section 81 of the Atomic Energy Act of 1954 is changed to require that the rates reflect fair market value, that change may make it more difficult to support university research aiming at improving food irradiation technology. Cesium-137 is on hand and before

processing it may represent a negative asset. The old provision which only requires "reasonable compensation to the Government for such material" may leave us with more flexibility in promoting research and development for the benefit of the consumer.

Under the heading: ESTABLISHMENT OF JOINT OPERATING COMMISSION FOR FOOD IRRADIATION on page 11, a Joint Operating Commission for Food Irradiation under the Department of Agriculture would be established. I believe that such a Commission would be beneficial. It would be better, however, that the coordinating role be more centrally located and continue with the existing Subcommittee on Interagency Radiation Research and Policy Coordination of the Federal Coordinating Council for Science, Engineering, and Technology.

Mr. Chairman and members of this Committee, I believe this is a good Bill and hope it will be passed by The Congress. I thank you for the opportunity to present the findings of the IAST's Task Force as well as my point of view.

12. USE OF ENERGY

The overall energy used in the irradiation process tends to be less than in many other processes. [Brynjolfsson, 1978] The use of the process will also tend to reduce the food losses. Therefore,

> the irradiation process will tend to reduce the overall energy used in the food industry.

APPENDICES WITH THE STATEMENT

A. Task Force Members

B. BRYNJOLFSSON, A. 1985. Wholesomeness of irradiated foods: A review. J. Food Safety, 7(2), 107-126.

C. BRYNJOLFSSON, A. 1980. Food irradiation in the United States. Proceedings of th 26th European Meeting of Meat Research Workers; Colorado Springs, Colorado U.S.A. Vol. I, pp. 172-177. Prepared by the American Meat Science Association.

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WHOLESOMENESS OF IRRADIATED FOODS: A REVIEW

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ABSTRACT

The major findings in the wholesomeness studies on irradiated foods are reviewed. It is concluded that this process is ready for industrial applications and could be effectively regulated for the benefit of the consumer.

INTRODUCTION

The wholesomeness of irradiated foods (more specifically, electronically preserved foods or foods preserved by fast electrons) has been studied thoroughly during the past 37 years by private, national, and international organizations. The Office of the Surgeon General of the U.S. Army *(OTSG)* sponsored extensive studies in the fifties and early sixties. Based on these studies, the Surgeon General concluded in 1965 that foods irradiated with doses up to the sterilizing dose of 56 kilogray (kGy), which is equal to 5.6 million rad, were safe to eat and issued the following statement (The Surgeon General of the U.S. Army 1965): "Foods irradiated up to absorbed doses of 5.6 megarads with a cobalt 60 source of gamma radiation or with electrons with energies up to 10 million electron volts have been found to be wholesome, i.e., safe, and nutritionally adequate." The conclusions were based on extensive studies conducted between 1948 and 1965.

At the international level, joint expert committees sponsored by the United Nations' Food and Agricultural Organization (FAO), International Atomic Energy Agency (IAEA), and World Health Organization (WHO) were convened in 1964, 1969, 1976, and 1980 to consider the question of wholesomeness of irradiated foods. At the last meeting in Geneva from 27 October to 3 November, 1980, the "Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food" (JECFI), reviewed the extensive data collected up to that time. After a thorough review, the Committee concluded that irradiated foods are safe and wholesome. The Committee's main conclusions were (JECFI 1981): "...

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that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required." The report also states that: "irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems."

The studies and the reports which led to these conclusions were extensive, and the evaluation thorough. The different subspecialties of the wholesomeness question of irradiated foods had been reviewed in the previous years by groups of scientists in the different subfields. The JECFI members were from many countries, but served there as individuals and solely as experts in their respective fields. The report summarizing the conclusions is brief, 34 pages (JECFI 1981).

The FAO/WHO Codex Alimentarius Commission was established to implement the Joint FAO/WHO Food Standard Program for foods in international trade. Following the JECFI report, the Commission, through the Codex Food Additive Committee, developed two standards for irradiated foods (Codex Alimentarius Commission 1984): (1) International General Standard for Irradiated Foods and (2) International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods. At its 15th session in July, 1983, the Commission, representing 122 member countries, accepted the General Standard and the Code of Practice for Irradiated food.

In accordance with General Agreement on Tariffs and Trade, GATT, these Standards should be accepted by the member countries to GATT, unless there is a good reason for not doing so.

JECFI members were well aware of the many studies that had been carried out on foods irradiated with doses above 10 kGy. The Committee limited its conclusions, however, to foods treated with doses less than 10 kGy, because important studies of foods irradiated at the higher dose levels were still being conducted. In particular, the animal feeding studies on irradiation sterilized chicken conducted by Ralston Purina Company for the Office of the Surgeon General of the U.S. Army, and later continued by U.S. Department of Agriculture, had not been completed by November 3, 1980, the date JECFI ended its meeting and announced its conclusion. (JECFI 1981)

The Radiation Sterilized Chicken Studies

The studies, which included long-term multigeneration studies on dogs, rats and mice fed irradiation sterilized (electronically preserved) chicken meat, have now been completed. Preliminary evaluation has been made for the United States Department of Agriculture (USDA) by an outside

consulting firm in this field, Tracor Jitco, Inc., (1983). No differences were found among the four groups studied: 2 control groups and 2 test groups, in each and every one of the many toxicology tests and mutagenesis tests. The control groups were fed either enzyme inactivated meat stored frozen (the F group), or meat made shelf-stable by heat sterilization (the T group). The test groups were fed either electron irradiated meat (the E group), or gamma-ray irradiated meat (the G group). The average irradiation dose used for sterilizing the frozen meat was 58 kGy, (45 kGy minimum dose, 68 kGy maximum, median 56 kGy, and an average of 58 kGy). The temperature during irradiation was on the average about −25 °C. After irradiation the meat was kept at room temperature, about 24 °C. Although no detrimental effect as a result of irradiation could be discerned, some questions have been raised about some findings in two of these studies: the long term multigeneration mouse study and the Drosophila mutagenesis study (Anon 1984). A few excerpts from the main conclusions in the Tracor Jitco's report will be sufficient for this overview. The reviewers found: (1) Main Conclusion: ". . . all the meat diets, frozen control, thermal control, gamma irradiated test diet, and electron irradiated test diet to be indistinguishable in nutrients and essentially free of common toxic contaminants." (2) Neoplasms: Among the meat fed mice, group F (frozen control) had the highest incidence of total neoplasms in both sexes. Group G (gamma-irradiated) had the lowest incidence among the male group, while group E (electron irradiated) had the lowest among females, the latter being significantly lower when compared to F (frozen control) females. Group G females had the highest incidence among the meat fed groups, although this was not significant when compared to group F. Renal tubular neoplasms occurred at low incidences only in meat groups T (thermal control) and F, and were observed only at terminal sacrifices. Group G and E each had four cases of interstitial (Leydig) cell tumor, a rare slow growing benign testicular tumor. Group F had only one case of these tumors, significantly lower than the two test groups. Using the National Toxicology Program's Statistical Analysis Package (NTPSAP), however, no significant difference could be shown between groups F and G in incidental tumor test or time-to-tumor analysis. (3) Growth and body weight: "Through four generations, each of the four chicken diets supported growth to adult body weight approximately equally." (4) Reproductive performance: "In reproductive performance through three generations, the only important difference seen in mice fed diets F, T, G, and E was comparatively decreased fertility in group T. Among the groups fed irradiated chicken, there was no reduction in the number of offspring born, no increase in the number of stillbirths, and no reduction in survival of pups."

FDA's Division of Pathology has reviewed the pathological slides and found among other things that (Anon 1985): (1) There was no increase in interstitial cell hyperplasia in the testes of these animals, and no evidence of progression of testicular lesions from hyperplasia to neoplasia. (2) There were no demonstrable toxic lesions (e.g., atrophy or necrosis) in the testes which could have contributed to the pathogenesis of neoplasia. (3) All the testicular tumors were unilateral, i.e., none of the tumors were bilateral. Only one of the testicular tumors was interpreted as malignant tumor. (The National Toxicology Program, special subcommittee that reviewed the slides found no malignancy). (4) A majority of the tumors were reported in animals at the time of terminal sacrifice (i.e., two years of age). Three of the animals with testicular tumors which died before the terminal sacrifice had other lesions also which may have contributed to their early mortality. (5) Cystic vascular interstitial cell tumors mimic other tumors and the reported incidence of interstitial tumors is probably not represented fully in the historical control data.

The number of test groups needs clarification. While the two groups fed irradiated meats were treated in the reports as if they were independent, they actually are not independent, but equivalent. The action of the gamma-rays is due to the fast electrons they produce. The irradiation effects are, thus, produced by fast electrons in both cases.

Some of the early researchers named the process correctly electronic preservation (Huber 1945). The overused words radiation and irradiation are used for many kinds of radiations, including nonionizing radiations. They are often used in the context of radioactive fallout and destructive power of nuclear weapons, for alpha emitter radiations and neutron radiations. The use of the words radiation and irradiation of foods for electronic preservation is therefore often misleading.

The chemical and any toxicological effects are initiated by the fast electrons produced by the gamma-rays, just as if the food had been irradiated with electrons from an accelerator. Thus, the gamma-ray irradiated, and the electron irradiated meats, from a toxicological point of view, are in fact both irradiated by electrons. Dose rate effects are not important in the case of meats, as confirmed by the analyses of the radiolytic products (Merritt *et al.* 1978), with the exception of the water soluble and highly reactive thiamine (Thomas *et al.* 1981), which is of no consequence in the present context.

The use of two positive control groups, also, needs clarification. When the studies were initiated, the scientists at a FDA hosted meeting on the subject could not decide which was better as control: the frozen stored meat or the heat sterilized meat stored without refrigeration. Some

contended that the heat sterilization could destroy some natural toxicants in the meat. Also, the radiation sterilized meat would replace in the market place the heat sterilized meat. The comparison should therefore be made between these two processes. Others felt that the heat sterilization process could possibly produce minute amounts of toxic substances, and therefore the frozen stored meat should serve as control. No data were available to support strongly one or the other contention. Many felt that such data on the effect of heat sterilization were needed. The decision was to use both groups. Also, the two positive control groups if considered equivalent correspond to double the number of animals in one control group which would improve the overall statistics.

The reason for selecting the two separate test groups was somewhat similar. It was difficult for many to accept as unequivocal that the two test groups were equivalent from a toxicological point of view.

When the studies were planned, it was of course well known that the mice were mainly herbivores. It was in question how much protein they could tolerate in the diet. Still, in a study of this kind, it was reasonable to go as close as possible to the tolerable limit of protein content in the diet. The renal problems in the four meat eating groups were anticipated. The fifth group, the negative control, fed standard lab diet had less of a problem in the renal system.

Drosophila Mutagenesis Study

Several different kinds of mutagenesis studies were conducted, and in all the tests, the four meat groups were equivalent to each other. In one of them, the test organism was the fruit fly *Drosophila melanogaster*. Evolution did not develop the fruit fly to consume or thrive well on meat, which appears toxic when fed in excessive quantities. The fruit fly has been used, however, extensively in mutagenesis studies and hereditary research, ever since Thomas Hunt Morgan and his associates at Columbia University researched the subject in the early part of this century. It was therefore traditional to use this organism in chromosomal studies. When tested on the irradiated chicken meat no mutagenic effect was observed. Nor had any mutagenic effect been observed in previous tests on irradiation-sterilized beef and ham (Mittler 1979). Fewer progeny developed from all the groups fed diets containing chicken meat than from those fed a standard diet. The scientists at Ralston Purina noted, however, that fewer progeny developed from diets containing chicken meat irradiated with Co-60 gamma-rays than from those fed on other meats. Several factors could affect the number of progeny. For example, the viscosity of the diets varied slightly, and was observed to affect the

number of progeny that developed. Because the water holding capacity of the irradiated meats is slightly less than of the nonirradiated meats, the viscosity of the irradiated meat will be less when the diets are made up with equal amounts of fluid. The viscosity is difficult to measure. The irradiation will shorten some of the long protein molecules. This dissociation and variation in the viscosity is likely to make some of the amino acids more available, and therefore to cause greater toxicity in the fruit fly. The observations could possibly be explained in this way. The statistical fluctuations in these observations were large, and it was actually difficult to determine if the effect was in fact real.

It had previously been questioned if antivitamins could be produced in the processing of the meat. None have ever been observed to be produced by irradiation of foods. Addition of vitamins to the Drosophila diets containing the meat appeared to enhance slightly (statistically insignificant) the toxicity of the meat. So, if there was an effect of irradiation, it was not brought about by antivitamins, as initially suggested by some. Several separate antivitamin studies using mammals have also proved negative.

The Drosophila studies were for testing possible mutagenicity of meats that were processed in different ways. They were never intended to become reproductive or toxicological studies. Mammals are considerably more relevant than Drosophila for evaluation of toxicity of human food. Professor Sidney Mittler, who previously had done similar studies (Mittler 1979), remarked when asked about his view: "The fact that fewer progeny grew out of the meat diets is comforting, because it indicates that the larvae were eating the meat. That was important in these mutagenesis studies."

Comparison of Radiation Effects on Living Organisms and on Food

The effect of irradiation processing (electronic preservation) on foods has most likely been more thoroughly investigated than the effect of any other food preservation process. Irradiation of living organisms is well known to be harmful and to be mutagenic. Mental association with these effects made many believe, incorrectly, that irradiated foods would produce some similar effects. The opposite is closer to the truth.

The radiation damage to a living organism is based on the damage to its macromolecules, such as DNA and proteins. The DNA is about a million times larger than the basic units of food, such as amino acids, fatty acids, and monosaccharides. The number of chemical changes in a molecule are

roughly proportional to the molecular weight (Brynjolfsson 1981). Therefore, the DNA is roughly about a million times more sensitive to radiation than the basic units of food. It follows that living organisms, the parasites and the spoilage microflora, are much more sensitive to irradiation than the basic units of food. About one per cent or less of the basic molecular units of food are affected by irradiation doses that sterilize the food (Brynjolfsson 1981). These changes are much too small to be measured in any protein efficiency study. This has been confirmed in many experiments, including the studies on sterilized (58 kGy) chicken (Tracor Jitco 1983). Heat sterilization destroys or changes a much larger fraction of these basic units of food. For example, most enzymes are easily inactivated by heat, but not by irradiation. The macromolecules, such as DNAs and the proteins, which irradiation affects the most, are generally toxic in their intact form and must be digested (hydrolyzed) before they enter the blood or lymphatic system.

The Effects of the Radiolytic Products

Although the number of chemical reactions as a consequence of irradiations (more specifically, as a consequence of electronic preservation) is smaller than in corresponding heat processes, the question could be raised, whether the products of irradiation are significantly different, and if some toxic compounds could be produced. These compounds would be produced in minute quantities. The animal feeding studies have failed to find any harmful effect. The conservatives in the field contend, however, that the animal feeding studies are too insensitive.

At the U. S. Army Natick Laboratories in Massachusetts, as well as at many other laboratories throughout the world, very extensive analyses were made of the radiolytic products formed in irradiated food (Taub *et al.* 1976; Merritt *et al.* 1978; Simic 1978; Diehl 1978; Nawar 1978; Ward 1978; Taub *et al.* 1980; Thomas *et al.* 1981; Basson 1983; Merritt and Taub 1983; Simic 1983; Nawar 1983; Merritt *et al* 1983; Taub 1983). The actual analyses of the components formed in the food and of the reaction products in the many model systems, as well as the theoretical estimates, gave a consistent picture of what changes take place. It was shown that the products and their concentrations could be predicted from the composition of the food, the radiation dose and the temperature (Merritt and Taub 1983). The results of these analyses were then given to an independent group of biochemists and toxicologists for evaluation (F.A.S.E.B. 1977, and Supplements I and II in 1979). This evaluation was based on the known toxicity of these compounds, which in turn had been derived

from separate tests and observations. Most of the compounds are innocuous and standard hydrolyses products of foods. Others may be more problematic. Benzene is produced in parts per billion quantities at the highest irradiation doses, but it is also found in many natural, nonirradiated foods including meat, fish, vegetables, nuts, dairy products, eggs, and beverages (F.A.S.E.B., Supplement I, 1979). It is produced at about the same level as in the heat sterilization process (Chang and Peterson 1977). It is found in many times larger quantities in eggs and many other foods (MacLeod and Cave 1976; and Van Straten 1977)

This chemical analysis approach to wholesome evaluation, in principle, amounts to concentrating the radiolytic products and feeding them to the animals. These analyses and evaluations, most likely, more than any animal feeding studies, convinced the skeptics that irradiated foods are safe.

Public Acceptance

While a large number of scientists, including many considered to be health authorities, are familiar with the results of the studies on irradiated foods, still many more are not. The extensive literature on the subject is scattered, often in publications with limited distribution. It is difficult, therefore, to get an overview and to discern the significant contributions. Although many health officials recognize the safety of irradiated foods, they prefer to proceed slowly, to give the critics an opportunity to make their points. It would be helpful if layfolk became more knowledgeable about the process. Epstein and Goffman (1984) proposed work of extracting and concentrating the radiolytic products and then testing them. This had already been done, in principle, (F.A.S.E.B. 1977, 1979, and 1979) as indicated above.

Many other individuals have been profoundly concerned about the impending general approval of the process (Anon 1984). Some of the concerns include the following: (1) Two Russian studies show detrimental effects in rats fed food irradiated with gamma-rays at doses of 8 and 6 kGy (Kamaldinova 1970, and Shillinger and Osipova 1970). (2) Three Indian studies showed abnormal white blood cells in children and monkeys and rats fed irradiated wheat (Baskaram and Sadasivan 1975; and Vijayalaxmi 1975 and 1978). (3) Two Indian studies showed that irradiated wheat, maize, sorghum, pearl millet, potatoes, and onions produced more aflatoxins than the non-irradiated samples (Priyadarshini and Tulepule 1976 and 1979).

At the request of U.S. Army Natick Laboratories the Russian studies were reviewed in 1970-71 by several scientists with expertise in this field.

Each found them poorly designed, and recommended that they be ignored. In the experiments by Kamaldinova (1970) the basic diet did not meet the modern standards. The conclusions of the author were supported by statistically insignificant data. The changes in fat metabolism were claimed on the basis of tributyrinase measurements. However, an analysis of the data shows that liver tributyrinase activity was identical in the parent test group, first generation test group and in the first generation control group. Only the parent control group had slightly lower activity.

In the studies by Shillinger and Osipova (1970) the diets did not meet modern standards; the 30 mg per day of calcium was inadequate and the low calcium/phosphorous (Ca/P) ratio about 30/100 aggravated this deficiency. The test diets were mistreated. Fresh fish irradiated at 6 kGy was stored between −1 and +7°C for a period of two months. Considerable bacteriological as well as chemical changes can be expected. The control was kept frozen. Lack of data in support of the conclusions and contradictory statements made evaluation difficult. The JECFI (1976) was well informed about these papers.

Soviet authors (including the above) have subsequently published several papers confirming the safety of the irradiated foods: Bronnikova and Okuneva (1972); Kamaldinova, Shillinger and Zaitsev (1977); Zaitsev and Osipova(1981); Zaitsev and Maganova (1981); Shillinger and Kamaldinova (1973); Zajcev (= Zaitsev), Shillinger, Kamaldinova, and Osipova (1975).

The data reported by Bhaskaram and Sadasivan (1975), and Vijayalaxmi (1975 and 1978) on the possible chromosomal aberrations are meager and have large statistical fluctuations. Kesavan (1978), who had an opportunity to consider the data more closely, reported that the: "experiments were not designed well, and consequently their results were found to be imprecise . . . It is concluded that the NIN data failed to demonstrate any mutagenic potential in irradiated wheat". NIN refers to National Institute of Nutrition, Hyderbad. It is helpful to take note of the fact that the 1.8% polyploidy observed in these studies in children receiving irradiated wheat is in the normal range, while the 0% polyploidy in children receiving unirradiated wheat is abnormal, and probably impossible. Several studies were undertaken to check if there was any mutagenic effect in irradiated wheat: George *et al.* (1976); Tesh *et al.* (1977); Reddi *et al.* (1977); Chauhan *et al.* (1977); Murthy (1981). Additional studies contracted out by The International Project in the Field of Food Irradiation could not confirm any mutagenic effect (JECFI. 1976).

The wholesome studies on poultry meat, irradiation sterilized with the high average dose of 58 kGy, included several investigations of possible

chromosomal effects. No chromosomal effects from consumption of irradiated poultry meat could be discerned. (Tracor Jitco, Inc. 1983)

In the aflatoxin studies by Priyadarshini and Tulepule (1976 and 1979) the samples were heat sterilized before infection with fungi. Such a heat sterilization process, like many other food processes, destroys natural antifungal conponents in the food (Sharma *et al* 1981). The observations, therefore, are of little or no relevance to irradiation of raw agricultural commodities, such as potatoes, onions, and wheat which contain antifungal components. Related are the studies by Schindler *et al.* (1980), who irradiated *Aspergillus flavus* and *Aspergillus parasiticus* and who obtained by mutation or selection an organism that produced more toxin than the unirradiated culture. While their test tube experiments may not be directly applicable, they remind us that caution must be observed, when we selectively destroy more of some strains or organisms than of others. In this respect irradiation, like any other food process, can change the naturally occurring or normal microflora. Several authors have investigated the proposition of aflatoxin production: Bullerman *et al.* (1973); Sharma *et al.* (1978); Behere *et al.* (1978); Sharma *et al.* (1979). JECFI (1981) was well informed about these Indian studies and scrutinized them thoroughly, like any other report that could give a hint about possible harmful effects.

The comments in the penultimate paragraph of the Science News article (Anon 1984) are about the kidney problems in mice fed protein rich diets and about reduced number of offsprings from fruit flies fed meats. As mentioned above, the very protein rich diet causes great stress on the mice, especially their renal system. Toxicologists evaluating these data take this into account. Furthermore, the overall incidences of neoplasms in both sexes happened to be most common in the frozen control group and not in the test groups fed irradiated (with the high average dose of 58 kGy) poultry meats. Reasonably, this higher incidence in the frozen control is due to a statistical fluctuation. The Science News comment about Drosophila studies is likewise based on misunderstandings, as discussed above.

> *There has been no lack of critics, skeptics, and scientists that thought irradiation of food might produce harmful effects. Every suggestion of these skeptics had been thoroughly and fairly reviewed, and followed up by experiments. This had contributed greatly to an exceptionally thorough evaluation, during the last 30 years, of the food irradiation process.*

The Microbial Mutants

Sometimes, a question is raised about the possibility of producing new and harmful microbial mutants. This is an important subject. Many very able microbiologists have been concerned and have researched it for many years (Among others: Erdman *et al.* 1961; Thatcher 1963; Christensen and Kjems 1965; Licciardello *et al.* 1969; Epps and Idziak 1970; Previtte *et al.* 1970; Cliver 1977; Maxcy 1977).

At the request of FAO and WHO, the subject was considered at a meeting of the Board of the International Committee on Food Microbiology and Hygiene of the International Union of Microbiological Societies on 16 December, 1982. The Board met at the Royal Veterinary and Agricultural University in Copenhagen.

After analyzing the scientific knowledge available to date, the Board was satisfied that there was no cause for concern and that modern techniques were adequate to control the situation. Food irradiation was considered to be an important addition to the methods of control of food-borne pathogens and not to present any additional hazards from shifts in the microflora or changes in the attributes of the microorganisms (Anon 1982).

Most processes based on heat, drying, freezing, or use of chemicals will produce mutants, or selectively favor some mutants that are constantly being produced by nature. The irradiation process is no exception. The mutants produced or selected by the irradiation method have usually been less competitive than the unmutated natural flora (Previtte *et al.* 1970; Cliver 1977; Maxcy 1977). Radiation usually destroys the genes rather than creates them, Therefore, the mutants produced by irradiation are missing some of the genes that are important for their survival in the real world (and not isolated in a test tube). They often require a rich medium for outgrowth. The exposure of the bacteria in our environment to the background radiation produces many more mutations than we would ever create in food irradiation. Still, much more numerous are the mutations produced by heat or by chemicals.

A problem of slightly different nature is the selective destruction of some organisms more than others when substerilizing doses are used. Lack of natural competition may then favor the growth of some strains or microorganisms. In this respect irradiation is analogous to other food processes. This underscores that food irradiation, like other processes of food for the public, should be in the hands of food technologists, microbiologists and others knowledgeable in the field.

Labelling

The question of labelling irradiated foods is a separate matter. The JECFI (1981) noted that: "... It was therefore not thought necessary on scientific grounds to envisage special requirements for the quality, wholesomeness, and labelling of irradiated foods." Some other consulting groups have recommended against mandatory labelling (Anon 1983).

If irradiated foods must be labelled, and if they are subsequently processed into different other products (e.g., orange juice made from oranges disinfested by irradiation) or become an ingredient (e.g., condiment) of another product, it must be resolved at what stage and at what fraction the declaration of irradiation is no longer required.

Proponents of labelling contend that this is a new method, and one should have the choice of not eating irradiated foods, and to have that choice, the food must be labelled. The proponents of nonmandatory labelling point to the fact that: chemically sprout inhibited potatoes and onions are not labelled; chemically treated fruits and vegetables for disinfestation and for preventing or retarding rot are not labelled; poultry meat and other foods washed in chlorinated water are not labelled. Therefore, it could be misleading to mandate labels only on irradiated foods. The consumer would in fact not be able to make an educated choice.

Irradiated foods usually look the same, and are to be handled in the same manner as their nonirradiated counterparts. If that is not the case, then a labelling informing the consumer about the special handling would be needed.

In the "Codex General Standard for Irradiated Foods", (Codex Alimentarius Commission, 1984) the labelling requirements are: (1) Inventory control. For irradiated foods, whether prepacked or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment and the lot identification. (2) Prepackaged foods intended for direct consumption. The labelling of prepackaged irradiated foods shall be in accordance with the relevant provisions of the Codex General Standards for the Labelling of Prepackaged Foods. (3) Foods ip bulk containers. The declaration of the fact of irradiation shall be made clear on the relevant shipping documents.

The labelling requirements are currently under revision by the Codex Commission. In March 1985 the Committee on Food Labelling recommended mandatory labelling. This recommendation will be considered by the full Commission.

Radiation Sources

The radiation sources are stipulated in section 2.1. of the Codex General Standard for Irradiated foods: Radiation sources. The following types of ionizing radiation may be used: (1) Gamma-rays from the radionuclides Co-60 or Cs-137. (2) X-rays generated from machine sources operated at or below an energy level of 5 MeV. (3) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

The energy limits are for preventing any problems of induced activity in the foods. These radionuclides are extensively used in hospitals and for sterilization of medical products. The nuclear regulatory controls of the radionuclides are necessarily strict and often cumbersome. The industry usually prefers, therefore, electron accelerators which provide most of the industrial radiation sources today, mainly for crosslinking and polymerizing plastics.

Environmental Concern

Irradiation of food will reduce the food losses, and it will reduce the amount of energy used in the food industry (Brynjolfsson 1978). It will reduce the use of insecticides, such as halogenated hydrocarbons, and it will reduce the use of some other undesirable chemicals, such as ethylene oxide. It will reduce also the amount of food borne diseases of microbial or parasitic origin. If cesium-137 sources are used, a waste product from the nuclear industry would be put to use under tight control. Cobalt-60, on the other hand, would be intentionally produced for the purpose of irradiation and would increase the total load of radioactive isotopes in the environment. Although the technical problems of operating safely in the hands of skilled people are small, the administrative problems of assuring safe operation may be more difficult. It is important, therefore that the controls of these sources be enforced strictly. The nuclear regulatory controls are already in place. In addition the facilities could be inspected by the food health authorities. As long as these controls are strictly enforced, the environmental impact of the isotope sources is small. When electron accelerators are used, the technical and administrative problems of assuring safe operation are small, and undesirable effects on the environment are minimal.

In the Codex General Standard for Irradiated Foods, (Codex Alimentarius Commission, 1984) among other things, it is required that: (1) Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by competent national authority. (2) The facilities shall be designed to meet the requirements of safety, efficacy

and good hygienic practices of food processing. (3) The facilities shall be staffed by adequate, trained and competent personnel. (4) Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry. (5) Premises and records shall be open to inspection by appropriate national authorities.

In the 5 points above the verb "shall" is used rather than "should", which is more common in the Codex standards. These verbs were discussed at the Codex meetings. It was felt that strict requirements in these areas would help inspection and control for assuring good manufacturing practices.

In the sections on hygiene of irradiated foods and technological requirements, it is among other things required that: (1) The food should comply with the provisions of the Recommended International Code of Practice—General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1, 1979) and, where appropriate, with the Recommended International Code of Hygienic Practices of the Codex Alimentarius relative to a particular food. (2) The irradiation of food is justified only when it fulfils a technological need or where it serves a food hygiene purpose and should not be used as substitute for good manufacturing practices.

CONCLUSION

As summarized above, the data on the animal feeding studies conducted at a great many laboratories as well as the radiation chemistry data indicate that irradiation of foods does not introduce harmful effects and that the process is ready for practical applications for the benefit of the consumer. These benefits include reduced use of chemicals, such as some pesticides (halogenated hydrocarbons) and some bactericides (ethylene oxide), and for extending shelf-life of some products. As this is done it is important that good manufacturing practices be applied.

The Codex Standard for irradiated foods in international trade form a reasonable basis for regulations within the different countries. The regulations would make it possible for the health authorities to control the irradiation process to the extent needed. In the United States, the irradiation facilities for processing of food could be approved and inspected, not only by the U. S. Nuclear Regulatory Commission (NRC), but also by FDA and USDA.

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FOOD IRRADIATION IN THE UNITED STATES

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INTRODUCTION

Conceived some thirty years ago, as a practical method of preservation, food irradiation, especially the wholesomeness aspect, has been studied extensively. No other food preservation method has been so thoroughly scrutinized. As the methodology for detecting harmful effects in food have improved, we have become more confident that this is a safe process; and the results of these comprehensive research and development allow us now to predict that in the eighties we will see this new method widely accepted, and irradiated foods move in international trade.

The early man's "wholesomeness studies" of food processes were obtained by observing the effect on humans eating the food. These tests were direct and relevant, although less sophisticated than our wholesomeness testing of irradiated food. The cavemen invented the cooking of food and the smoking of meat and fish, as well as sun drying, to prevent the microbial spoilage. Use of salt and oil to preserve food is mentioned by Homer. Recent studies indicate that salt and curing by nitrates and nitrites was used already by the Sumarians some 5000 years ago. In the seventeenth century, following Leeuwenhoek's discovery of the microbes under the microscope, we see the first steps towards heat sterilization, which led to Nicholas Appert's pioneering research in the years 1787-1810. Refrigeration and freezing has long been known to extend shelf-life of food, but not before about 1865 did commercial freezing begin. Today, we see these old methods being improved and modified.

Irradiation, the newest method, is perceived by many to be radically different from the older methods. In the past, when we discovered a new method, we did not stop using the old methods; instead, we used the new method to solve problems we could not, or could barely solve before. That is the way it will be also with food irradiation. It is not a panacea, but sometimes it is the best method.

Let us consider a need to sterilize dryed, powdered, and packaged onions. The alternative to irradiation is often fumigation with ethylene oxide. Before fumigation, we must rehydrate the product by steam, preferably for 24 hours. We then expose it to the ethylene oxide for about 16 hours, remove the ethylene oxide by flushing the product with air; dry it; and regrind it, as the powdered onions will have clumped together. Similarly involved procedures are required for effective sterilization of many other food ingredients, condiments, food colors, food enzymes, as well as dryed animal feed.

Irradiation, on the other hand, is relatively a simple process; it does not require exposure to steam; it can be applied to the product as is without repackaging. It is analogous to x-raying our luggage at the airport. The medical industry is already making extensive use of this method because it is simple, reliable, and less damaging to their product than some of the older methods.

Historical milestones. Before the end of the century, scientific curiousity established that x-rays could kill pathogenic microorganisms(1). In 1909, a patent for destruction of Lasiderma beetles in tobacco by means of x-rays was issued in USA. In 1930, O. Wust obtained a patent in France for food preservation by irradiating radiation, but the scientific evidence for the feasibility of industrial application was still meager. In 1943, Proctor, Van de Graaff, and Fram at MIT reported on the "Effect of x-ray irradiation on the bacterial count of ground meat"(2). In 1947, Brasch and Huber(3) showed that high dose-rates, exclusion of oxygen, and irradiation in frozen state reduced undesirable side reactions. In 1948, The Office of Surgeon General's Medical Nutrition Laboratory initiated some exploratory animal feeding studies on irradiated food, and in September 1950, Swift & Co. initiated a major multigeneration, long-term animal feeding study on irradiated beef(4). These early wholesomeness studies did not find any harmful effect from consumption of irradiated food.

In 1953, a National Academy of Sciences ad hoc committee recommended that Office of the Quartermaster General correlate and support research in this field. In 1954, The Surgeon General and the Quartermaster launched a systematic wholesomeness study of representative foods, shown in Table 1 and 2, with the aim of clearing irradiation of food as a process. In 1964, these studies were completed and The Surgeon General's scientists concluded that(5):

> "Food irradiated up to absorbed doses of 5.6 megarads with Co-60 source of gamma radiation or with electrons with energies up to 10 million volts have been found to be wholesome, i.e., safe and nutritionally adequate."

In 1960, the Atomic Energy Commission (AEC) (now under Department of Energy (DOE)) stepped up its efforts in food irradiation while Department of Army (DA) phased out its wholesomeness studies and stepped up its efforts in engineering and prepared for transfer of the technology to industry. All this changed in 1968 when Food and Drug Administration (FDA) turned down a 1966 petition by DA for irradiated ham. Previously, FDA had approved irradiated potatoes, wheat and bacon. In 1968, FDA revoked the approval for irradiated bacon.

At that juncture, AEC terminated its food irradiation program, and also DA wanted to terminate its food irradiation program, but was persuaded by scientists and Congress, in 1970, to continue its program. The basis for this request was that in spite of FDA's refusal to approve the petition for ham, nothing in these extensive

wholesomeness studies had shown harmful effects of irradiation.

The 1968 refusal by FDA to approve the petition for irradiated ham resulted in reduction of food irradiation programs throughout the world. Abroad, like in USA, scientists familiar with the problems recognized the merits of food irradiation process and pushed for formation, in 1970, of the International Project in the Field of Food Irradiation (IFIP), sponsored now by 24 countries, including USA, and the Organization for Economic Cooperation and Development (OECD), the International Atomic Energy Agency (IAEA), the Food and Agricultural Organization (FAO), and the World Health Organization (WHO), who is associated in advisory capacity.

TABLE 1. List of 54 Foods Tested on Humans in the Short-Term Toxicological Studies

11 Meat Items	5 Fish Items	9 Fruit Items	9 Cereal Product Items	14 Vegetable Items	6 Miscellaneous Items
Bacon	Cod	Dried apricots	Bread	Asparagus	Dessert powder
Corned beef	Haddock	Cherries	Crackers	Green beans	Powdered whole milk
Ground beef	Salmon	Dried fruit compote	Cereal bar	Lima beans	Peanut butter
Beef steak	Shrimp	Melon balls	Flour	Beets	Pineapple jam
Chicken	Tuna	Oranges	Macaroni	Brussel sprouts	Strawberry jam
Chicken stew		Orange juice	Nut roll	Cabbage	Sugar
Frankfurters		Peaches	Pound cake	Carrots	
Ground ham		Dried pears	Rice	Cauliflower	
Ham steak		Strawberries	Corn	Celery	
Ground pork				Cole slaw	
Sausage				Mushrooms	
				Peas	
				Sweet potatoes	
				White potatoes	

TABLE 2. List of 22 Foods Testing in Long-Term Toxicological Studies During the 1956 - 1965 Period

8 Animal Products	3 Sea Food Items	4 Fruits
Ground beef	Codfish	Fruit compote
Beef stew	Tuna	Pineapple jam
Chicken	Shrimp	Peaches
Chicken stew		Oranges
Pork loin	5 Vegetable Items	
Bacon		2 Cereals
Dried eggs	Green beans	
Evaporated milk	Cabbage	Flour
	Carrots	Corn
	White potatoes	
	Sweet potatoes	

The DA wholesomeness studies were restarted with a more thorough study on individual items and using thorough chemical analysis of the radiolytic products to extrapolate and interpolate the validity of these studies to a broad spectrum of food. The animal feeding studies were contracted out to industrial laboratories. In spite of the fact that these contractors were considered highly qualified, some of the major ones have faulted on their contracts. This has been costly and has also delayed petitioning FDA. Some other contractors have performed well and their results to date will be reported by Major Chapple at this conference. The in-house work at Natick Laboratories in food technology, microbiology and irradiation chemistry has progressed very well. Especially significant for the evaluation of the wholesomeness of irradiated foods has been the thorough analysis of the radiolytic products at Natick, carried out partly in-house and partly through well coordinated contracts with several universities as described by Dr. Taub at this conference.

The international cooperation in food irradiation has been very constructive. Important milestone was the evaluation in 1976 by IAEA/FAO/WHO Joint Expert Committee on Food Irradiation (JECFI) of the data on wholesomeness of irradiated foods, and its recommendation that five irradiated foods be considered unconditionally safe for human consumption and three others receive provisional acceptance. Subsequently, the influential Codex Alimentarius Commission developed General Standards for movement in international trade of these eight irradiated items (poultry, fish, potatoes, onions, wheat, rice, papaya, and strawberries). The standards received final acceptance in December 1979, at Step 8 of the Commission procedures. Simultaneously, the Codex Commission accepted also General Standards for Operation of Food Irradiation Facility for Treatment of Foods in International Trade.

In 1977, the cooperation in the field of radiation chemistry was expanded by formation of CORC (Coordinated Radiation Chemistry) program under the auspices of the International Project in the Field of Food Irradiation, as described by Dr. Elias at this conference. The radiation chemistry data, together with the animal feeding study data, will be used to seek a significant expansion of the acceptance of irradiated food in international trade. For this purpose, JECFI will consider, in Nov 1980, acceptance of food irradiation as a process for all major categories of foods irradiated with a dose less than 10 kGy.

Hygenization of food. Major benefits of food irradiation will derive from hygenization of food, i.e., freeing it from food spoilage and pathogenic microorganisms, parasites, and insects. In modern society, the quality of life has improved greatly because of higher hygenic standards than before in production, processing and distribution of food. The high hygenic standards have improved the health of the consumer (with its many associated

benefits); they have extended the storage life of the food; and they have increased radius of distribution. Still, advanced societies, like USA, could do even better. In a 1976 report from Comptroller General to the US Congress(6), it is estimated that two million cases of salmonellosis occur annually, resulting in losses of at least $300 million. Other reports have estimated the cost closer to $1500 million.

Microbial reduction. Besides salmonella, irradiation can be used to reduce or eliminate other food borne pathogens such as E. coli, Staphylococcus aureus, Clostridium perfringens and Yersinia enterocolitica. The resistance of microorganisms depends on the medium and the temperature. The vegetative organisms are often two or three times more resistant in dry, or frozen state, than in water, and they are more resistant when irradiated anaerobicly, i.e., in vacuum or in inert atmosphere like N_2, than when irradiated in oxygen atmosphere. Tables 3 to 7 give a rough guide to resistance of the microorganisms. Table 8 lists some of the applications and the corresponding dose range.

TABLE 3. Viruses (Ref. 8 to 12)

Microorganism	Irradiation Medium and Temperature	Dose in kGy for Reducing the Number by 10^6
Foot-and-mouth disease virus (FMDV) Types O, A and C	Calf kidney-cells lactalbumin	36
FMDV Type O	As above - wet	30
FMDV Type O	Frozen -60°C	36
FMDV Type O	20% peptone	36
FMDV Type O	0.1% peptone	10
Teschen disease virus	20% peptone	26
Vesicular stomatitis virus	20% peptone	12.3
Rinderpest virus	Frozen	Expected
Swine fever virus	Frozen	less than 36
African swine fever	Frozen	
Adenovirus	Eagle's minimum	25-30
Coxsachievirus	essential medium	25-30
Echovirus	plus 2% fetal	26-33
Poliovirus	bovine serum pH=7	26-31
Herpes simplex virus		26
Influenza virus A		28
Reovirus I		26
Simian virus		24
Rabies virus	10% brain emulsion	6

Reduction of parasites. Irradiation can be used to eliminate parasites. Trichinella spirales in meat can be sterilized, and thus the major pathological symptoms eliminated by a dose of only 0.15 kGy. Complete inhibition of maturation is obtained by a dose of 0.3 kGy (48). However, to kill Trichinella spiralis, Cysticereus

TABLE 4. Salmonella (Ref. 16 to 22)

Microorganism	Temperature	Dose in kGy Reducing the Number by Factor 10^6
Salm. heidelberg	Chicken 0°C	3.6
Salm. heidelberg	Chicken -18°C	6.0
Salm. oranienberg	Chicken 0°C	3.8
Salm. oranienberg	Chicken -18°C	5.5
Salm. typhimurium	Beef 5°C	3.5
Salm. typhimurium	Beef -18°C	6.0
Salm. thompson	Chicken 0°C	3.8
Salm. thompson	Chicken -18°C	5.0
Salm. newport	Chicken 0°C	3.0
Salm. newport	Chicken -18°C	5.0
Salm. gallinarum	Egg	2.6
Salm. gallinarum	Egg Frozen	3.4
Salm. senftenberg	Egg	3.0
Salm. senftenberg	Fish-meal	7.2
Salm. pullorum	Shrimp 5°C	4.5
Salm. choleraesuis	Oysters 5°C	4.5
Salm. enteritidis	Oysters 5°C	3.0
Salm. paratyphia A	Shrimp 5°C	5.1
Salm. paratyphia B	Crabmeat 5°C	6.0
Salm. paratyphia	Beef Liver 5°C	1.8
Salm. paratyphia	Horse Meat Frozen	6.4
Salm. typhosa	Crabmeat 5°C	6.0
Salm. typhosa	Corned Beef 25°C	2.4 - 4.8
Salm. wichita	Shrimp 5°C	6.0
Salm. meleagridis	Meat	2.3
Salm. meleagridis	Horse Meat Frozen	5.6
Salm. anatum	Fish-meal	4.8
Salm. tennessee	Fish-meal	4.8
Salm. pigmented str.	Fish-meal	6.6
Salm. derby	Pork 100°C	2.0
Salm. weltevreden	Pork 100°C	2.8
Salm. saint paul	Beef Liver 100°C	3.0
Salm. manchester	Beef Liver 100°C	2.2

TABLE 5. Vegetative Bacteria (Ref. 23 to 29)

Microorganism	Temperature	Dose in kGy Reducing the Number by Factor 10^6
Yersinia enterocolitica	Ground Beef 0°C	1.2
Yersinia enterocolitica	Ground Beef -30°C	2.3
Escherichia coli	Beef +25°C	2.1
Staphylococcus aureus	Beef	1.9 - 3.4
Staphylococcus aureus	Broth	2.7 - 3.1
Staphylococcus albus	Broth	2.4 - 3.1
Streptococcus faecalis	Broth	5.5
Streptococcus faecium	Broth	1.4 - 19
Streptococcus pyogenes	Oysters	6.0
Shigella sonnei	Crabmeat	1.6
Shigella paradysenteria	Oysters	1.6
Shigella dysenteria	Oysters	2.4
Mycobacterium tuberculosis	Broth +20°C	1.4
Aerobacter aerogenes	Broth +20°C	1.5
Aerobacter cloacae	Broth +20°C	1.6
Salmonella (diff. str.)	Dif. Med. Unfrozen	2.3 - 6
Proteus vulgaris	Oyster	1.2
Serratia marcescens	Broth	0.8 - 1.3
Pseudomonas fluorescens	Beef	0.8
Pseudomonas aeruginosa	Broth	1.3
Pseudomonas aeruginosa	Broth	0.4
Pseudomonas geniculata	Broth	0.8
Brucella abortus	Beef	2.0
Vibro parahaemolyticus	Phds. Butter	0.8
Vibro parahaemolyticus	Crabmeat	0.5 - 0.95
Lactobacillus hetero-fermentative	Broth	3.3 - 4.8
Lactobacillus homo-fermentative	Broth	4.9 - 6.6
Leuconostoc sp.	Broth	1.2 - 3.4
Sarcina flava	Broth	2.0
Moraxella-Acinetobacter	Beef	<55
Micrococcus radiodurans	Broth	<60

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TABLE 6. Spores (Ref. 30 to 42)

Microorganism	Temperature	Dose in kGy Reducing the Number by Factor 10^6
Bacillus subtilis	Dried Broth (N_2)	18
Bacillus subtilis	Dried Broth (O_2)	12
Bacillus pumilus	Buffer	18
Bacillus steareothermophilus	Broth	18
Bacillus cereus	Physiol. NaCl Sol.	14
Bacillus anthracis	Physiol. NaCl Sol.	12
Bacillus globigii		18
Cl. sporogenes	Buffer	13
Cl. welchii	Broth	8 - 22
Cl. botulinum 33A	Beef - frozen	24.5
Cl. b. 36A,33A,40B, 41B,53B	Phos. buffer	20 - 19
Cl. b. 77A,12885A, 98,62A	Phos. buffer	15 - 13
Cl. b. E, 51B	Phos. buffer	8 - 10
Cl. b. 33A-36A	Bacon 15°C	12.5
Cl. b. 62A(most resist.)	Ham 15°C	15.5
Cl. b. 12885A	Pork 15°C	21.5
Cl. b. mix. of 10 most resist str.	Ham -30°C	18
Cl. b. mix. of 10 most resist str.	Beef -30°C	20
Cl. b. 77A	Corned beef -30°C	12
Cl. b. 41B	Pork sausage -30°C	13.5
Cl. b. 53B	Codfish cake -30°C	16
Cl. b. E, Beluga, incub. 8°C	Haddock	9.7
Cl. b. E, Beluga, incub. 20°C	Haddock	17.1
Cl. b. F.Eklund, 83F - 80°C	Phos. buffer	13.0

TABLE 7. Fungi (Ref. 43 to 47)

Microorganism	Temperature	Dose in kGy Reducing the Number by Factor 10^6
Trichoderma viride	Citrus fruit	1.0
Trichoderma viride	Water	1.6
Phomopsis citri	Citrus fruit	1.2
Phomopsis citri	Water	1.5
Penicillum italicum	Citrus fruit	1.7
Penicillum italicum	Water	2.1
Penicillum expansum	Prunus fruit	2.3
Penicillum expansum	Water	2.1
Penicillum digitatum	Citrus fruit	1.9
Penicillum digitatum	Water	2.8
Penicillum camembertii	Water	1.2
Penicillum notatum	Water	1.8
Geotrichum candidum	Citrus fruit	2.5
Geotrichum candidum	Water	2.9
Monilinia fructicola	Prunus fruit	3.0
Monilinia fructicola	Water	3.1
Botrytis cinerea	Prunus fruit	3.2
Botrytis cinerea	Water	3.8
Diplodia natalensis	Prunus fruit	4.5
Diplodia natalensis	Water	4.5
Rhizopus stolnifer	Prunus fruit	4.1
Rhizopus stolnifer	Water	6.5
Alternaria citri	Citrus fruit	7.4
Alternaria citri	Water	9.0
Cladosporum herbanum	Prunus fruit	6.1
Cladosporum herbanum	Water	7.5
Gilbertella persicaria	Water	8.0
Saccharomyces carevisiae	0.85 NaCl kg gal.	3.0
Saccharomyces carevisiae	Water	2.5-3.6
Candida species	Broth	7.5
Torulopsis candida	Broth	3.6
Aspergillus niger	Water	2.7
A. flavus (spores)	Water	2.5

TABLE 8. Uses of ionizing radiation

1.	Inhibition of sprouting in potatoes and onions	0.03 - 0.1
2.	Sterilization of insects and parasites	0.03 - 0.2
3.	Killing of insects and parasites	0.5 - 5
4.	Reducing by 10^6 the number of vegetative bacteria, molds and fungi	1 - 10
5.	Reducing by 10^6 the number of dryed or frozen vegetative bacteria, fungi, and spores	2 - 20
6.	Reduction by 10^6 the number of viruses	10 - 40
7.	Sterilization of food	20 - 45

bovis (49) and many other parasites, a dose of 3 to 10 kGy is required. For example, to kill Anisakis larvae in herring (50), a dose of 10 kGy is required.

Reduction of insects. Sterilization of insects is usually obtained by doses in the range of 0.03 - 0.2 kGy (51). However, for some moth species (Sitotroga cerealla), doses in excess of 1 kGy are required. A dose of about 5 kGy is sometimes required for killing the insects (52) and the parasites.

Stabilization of food. Irradiation kills the microorganisms, but does not, otherwise, cause many chemical changes in the food. It thus does not destroy the enzymes in the food and it does not stop, therefore, its decomposition by protolytic and lipolytic enzymes. Also, irradiation does not prevent oxidative reactions, and it does not prevent recontamination by microbes and insects. When meats, poultry, and fish are to be preserved properly for long-term storage, we must use other means to inactivate the enzymes. At Natick, we use mild heat treatment (about 72°C) to inactivate protolytic and lipolytic enzymes in meats, poultry, and fish. We prevent oxidation by vacuum packaging the product in durable materials that are impermeable to oxygen and that withstand bacteria and insects. This way, we have produced at Natick a long series of highly acceptable meat, poultry, and fish products that are stable for several years at room temperature (53). Irradiation can also be used to reduce the microflora in raw meat, poultry, and fish products. The raw products should preferably be vacuum packed to prevent oxidation and recontamination. Use of low doses will reduce off-flavor caused by irradiation. On the other hand, the low dose makes it necessary to store the product at refrigerated temperatures or in frozen state.

Chemicleasrance and the magnitude of radiolytic changes. Irradiation damage to a molecule is approximately proportional to its molecular weight. The DNA molecule in microorganisms is the largest molecule there is, about 10^8 daltons. It is also essential for survival of the microorganisms. That is the reason that these organisms, like any other live form, are so sensitive to radiation. Food nutrients, such as proteins, lipids and carbohydrates, are digested into amino acids, fatty acids, and monosaccharides, with molecular weights about 150-250 before absorbed in the lymphatic system. The damage to these molecules is thus about a million times smaller than to the DNA molecules. A sterilizing dose that causes about 10-12 reduction of Cl. botulinum will cause a total number of all changes in these macro nutrients when irradiated in frozen or dry state that amount to about 0.24% in proteins, 0.3% in carbohydrates, and 0.4% in all lipids. Specific changes in the molecules are an order

or even several orders of magnitude smaller. When irradiated in unfrozen state, the total number of changes may be about 3 times greater. These changes are much too small to be measurable in any protein efficiency study, as confirmed in many experiments. This is especially true when we take into consideration that most of these changes result in products that are commonly found in food, as well as products that result from digestion of the food. We should remember in this context that the changes that occur during storage and especially during thermal processing often result in significant and measurable losses (5-40%) in protein value of the food. In the early experiments, the irradiated food was often improperly packaged in oxygen permeable films. It therefore became oxidized, as evidenced by high peroxide values. Some of the experimentors thought incorrectly that this was due to irradiation. This has caused some confusion. Irradiation makes it possible to extend the storage of food because it reduces or eliminates the microbial problem. Oxidation becomes then often the limiting factor. It therefore becomes important to eliminate oxygen from irradiated foods. Exclusion of oxygen also reduces detrimental oxidative reactions during irradiation.

In proteins, irradiation causes disruption of hydrogen bonds and unfolding of the molecules, similar to the changes caused by mild heat treatment. Relatively frequent, are also reductive deamination and decarboxylation. From alanine, we thus get ethylamine and propionic acid; from glycine we get acetic acid and methylamine, etc.

In polysaccharides, irradiation causes depolymerization and fragmentation into simpler molecules, such as glucose, maltose, maltotrose maltotetrose, maltopentose, carbon dioxide, hydrogen, formic acid, formaldehyde and acetone.

In lipids, irradiation causes abstraction of hydrogen and formation of a double bond, and splitting of the free fatty acids from the triglycerides. It may also cause scission at the carbon-carbon bonds resulting in a spectrum of aliphatic hydrocarbons.

Irradiation can also cause cross-linking, dimerization, and aggregation along with degradation. These changes are very small compared to the cross-linking and aggregation caused by heating. Indications are that these changes are similar in nature to those found in fresh food and in processed and stored food.

In unfrozen state, there are exceptions to the above quantitative estimates. This is especially evident for some of the micro nutrients such as the water soluble C-vitamin and B_1-vitamin that act as scavenger for the radiolytic product of water. These vitamins are destroyed about to the same extent as when the food is heat sterilized. The other soluble vitamins, B_2, B_6, and B_{12}, are also good scavengers when they are in pure solution. In food, they are often complexed with other molecules and then more stable. In this context, it should be kept in mind that most vitamins are unstable in long-term storage, and irradiation does not change that fact. The question has been raised if antivitamins (that are often found in food) could be formed. This was checked for vitamins B_1 and B_6 in meats and no antivitamin activity could be detected.

Energy savings. The energy consumed in the irradiation process is very small compared with other processes. Table 9 shows typical energy values for processing the food. More relevant for national energy savings is to include the energy savings in distribution and in the homes. Table 10 gives a few examples.(54)

Cost of irradiation processing. The irradiation costs, like the costs of many other processes, depend on the scale of production and the product flow plan. It is cheaper to irradiate the finished packaged product as it comes off the production line, than to use central service irradiation facilities, because of the significant cost of loading, shipping and unloading the product. Practice has shown, however, that central service irradiation facilities are needed especially in the beginning, when the quantities to be irradiated are small and the benefits great. Table 11 shows some typical costs of radsterilizing 100 million lbs per year of bacon in a 200 kwatt plant, operated 6000 hours per year at a beam utilization efficiency of 27%. The capital cost for the 4 MeV accelerator facility is about 1.8 million, for the 20 MeV accelerator facility 2.45 million, and for the Co-60 and Cs-137 facilities about 10 million. These costs are for simple, functionalistic facilities located between the production line and the storage rooms. (55-56)

TABLE 9. Typical Energy Values in KJ/KG Used for Processing of Food

Radpasteurization with 2.5 kGy	21
Radsterilization with 30 kGy	157
Heat sterilization	918
Blast freezing chicken from 4.4°C to -23.2°C	7552
Storing the product at -25°C for 3.5 weeks	5149
Refrigerated storage for 5.5 days at 0°C	318
Refrigerated storage for 10.5 days at 0°C	396

TABLE 10. Summary: Energy Use (KJ/KG) Associated with Different Chicken Processing Methods

Radsterilization cooked long chicken rolls	14,260
Radsterilization cooked individual servings	15,460
Retorted canned chicken meat	20,180
Frozen cooked long chicken rolls	27,550
Frozen raw cut-up chicken	46,600
Refrigerated raw cut-up chicken	17,760
Refrigerated and radpasteurized raw cut-up chicken	17,860

TABLE 11. Cost of Radsterilizing Bacon*

Source	5-Yr Plant Depreciation Costs in ¢	Operational costs in ¢ per lb	Total Cost in ¢ per lb
Co-60 isotope	2.03	1.2	3.23
Cs-137 isotope	2.03	0.32	2.38
10-MeV accelerator	0.49	0.43	0.92
4-MeV accelerator	0.36	0.40	0.76

*Plant Size: 100,000,000 lb per year

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Joint FAO/WHO Food Standards Programme

CODEX ALIMENTARIUS COMMISSION

CAC/VOL. XV – Ed. 1

CODEX ALIMENTARIUS VOLUME XV

CODEX GENERAL STANDARD FOR IRRADIATED FOODS AND RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE OPERATION OF RADIATION FACILITIES USED FOR THE TREATMENT OF FOODS

FIRST EDITION

FOOD AND AGRICULTURE ORGANIZATION
OF THE UNITED NATIONS
WORLD HEALTH ORGANIZATION
Rome, 1984

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INTRODUCTION

The FAO/WHO Codex Alimentarius Commission (the Commission) was established to implement the Joint FAO/WHO Food Standards Programme. Membership of the Commission comprises those Member Nations and Associate Members of FAO and/or WHO which have notified the Organizations of their wish to be considered as Members. By 1 July 1983 122 countries had become Members of the Commission. Other countries which participate in the work of the Commission or of its subsidiary bodies in an observer capacity are expected to become Members in the near future.

The purpose of the Joint FAO/WHO Food Standards Programme is to protect the health of consumers and to ensure fair practices in the food trade; to promote coordination of all food standards work undertaken by international governmental and non-governmental organizations; to determine priorities and initiate and guide the preparation of draft standards through and with the aid of appropriate organizations; to finalize standards and, after acceptance by governments, publish them in a Codex Alimentarius either as regional or world-wide standards.

At its 15th Session, held in July 1983, the Commission adopted a Codex General Standard for Irradiated Foods and a Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods to be sent to all Member Nations and Associate Members of FAO and/or WHO.

The Codex General Standard for Irradiated Foods was developed in accordance with the Codex Procedure for the Revision and Amendment of Codex Standards by the intergovernmental Codex Committee on Food Additives, which also deals with Food Processing, in close cooperation with the International Atomic Energy Agency (IAEA).

EXPLANATORY NOTES

This Standard takes into account the recommendations and conclusions of the Joint FAO/IAEA/WHO Expert Committees convened to evaluate all available data concerning

the various aspects of food irradiation, including the wholesomeness of foods processed by ionising energy. It also takes into account the recommendations of FAO/IAEA/WHO consultations on legislation and standardization of food irradiation.

This Standard refers only to those aspects which relate to the processing of foods by ionising energy. It is assumed in this Standard that foods processed by irradiation, like any other foods, will be subject to general food regulations relating to quality, hygiene, weights and measures and so forth. The provisions of this Standard encompass all foods irradiated up to an overall average dose of 10 kGy or lower. The Standard recognizes that the process of food irradiation has been established as safe for general application to an overall average level of absorbed dose of 10 kGy. The latter value should not be regarded as a toxicological upper limit above which irradiated foods become unsafe; it is simply the level at or below which safety has been established. In setting the overall average dose for the general application of food irradiation, it has been recognized that the required dose to achieve the desired technological effect is governed by "good irradiation practice". Applying the appropriate dose level is the key to the technologically and economically proper appliction of food irradiation.

Despite the many investigations designed to detect physical, chemical and biological changes in foods subjected to ionising energy, no satisfactory method for identifying food as having been irradiated has so far been developed. While certain effects can be identified, sufficiently precise methods do not exist for regulatory purposes. Therefore, control of commercial food irradiation can only be performed in the irradiation plant. Consequently, the Standard provides certain mandatory provisions concerning the facilities used and for the control of the process in irradiation plants.

As regards "labelling" attention is drawn to the following observation of the 1980 Joint FAO/IAEA/WHO Expert Committee on Wholesomeness of Irradiated Food : "Irradiated

foods would be subject to regulations covering foods generally, and to any specific food standards relating to individual foods. It was, therefore, not thought necessary on scientific grounds to envisage special requirements for the quality, wholesomeness, and labelling of irradiated foods". However, there can be a "technical ground" for specific applications of food irradiation and the declaration of this fact on the label. For instance, in the case of foods irradiated for the purpose of eliminating pathogens (which should not be stored together with potentially contaminated foods), a statement on the label and/or on the shipping documents of such decontamination treatment would be considered appropriate and informative to manufacturers, traders and others. The present Standard requires that shipping documents accompanying irradiated foods moving in trade should indicate the fact of irradiation together with relevant information so that good irradiation practice can be verified. The labelling of prepackaged irradiated foods intended for direct sale to the consumer is not covered in this Standard and has to be in accordance with the relevant provisions of the Codex General Standard for the Labelling of Prepackaged Foods. This General Standard is in the process of elaboration.

Members of the Commission are requested to notify the Secretariat of the Codex Alimentarius Commission - Joint FAO/WHO Food Standards Programme, of their acceptance of the Codex General Standard for Irradiated Foods, according to paragraph 4 of the General Principles of the Codex Alimentarius (see fifth Edition of the Commission's Procedural Manual).

Member Nations and Associate Members of FAO and/or WHO which are not Members of the Commission are also invited to notify the Secretariat if they wish to accept the Codex General Standard for Irradiated Foods.

The Codex General Standard for Irradiated Foods will be published in the Codex Alimentarius as a world-wide Codex Standard when the Commission determines that it is appropriate to do so in the light of acceptances received.

The Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods contained in this publication is intended for the guidance of Governments and is not governed by the acceptance procedure for Codex Standards.

CODEX GENERAL STANDARD FOR IRRADIATED FOODS (*)
(World-wide Standard)

1. SCOPE

This standard applies to foods processed by irradiation. It does not apply to foods exposed to doses imparted by measuring instruments used for inspection purposes.

2. GENERAL REQUIREMENTS FOR THE PROCESS

2.1. Radiation Sources

The following types of ionizing radiation may be used:

(a) Gamma rays from the radionuclides ^{60}Co or ^{137}Cs;

(b) X-rays generated from machine sources operated at or below an energy level of 5 MeV.

(c) Electrons generated from machine sources operated at or below an energy level of 10 MeV.

2.2. Absorbed Dose

The overall average dose absorbed by a food subjected to radiation processing should not exceed 10 kGy (1) (2).

2.3. Facilities and Control of the Process

2.3.1. Radiation treatment of foods shall be carried out in facilities licensed and registered for this purpose by the competent national authority.

2.3.2. The facilities shall be designed to meet the requirements of safety, efficacy and good hygienic practices of food processing.

2.3.3. The facilities shall be staffed by adequate, trained and competent personnel.

2.3.4. Control of the process within the facility shall include the keeping of adequate records including quantitative dosimetry.

(*) Revised version of the Recommended International General Standard for Irradiated Foods (CAC/RS 106-1979).

(1) and (2) See notes on page 4.

2.3.5. Premises and records shall be open to inspection by appropriate national authorities.

2.3.6. Control should be carried out in accordance with the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (CAC/RCP 19-1979, Rev. 1).

3. HYGIENE OF IRRADIATED FOODS

3.1. The food should comply with the provisions of the Recommended International Code of Practice - General Principles of Food Hygiene (Ref. No. CAC/RCP 1-1969, Rev. 1, 1979) and, where appropriate, with the Recommended International Code of Hygienic Practice of the Codex Alimentarius relative to a particular food.

3.2. Any relevant national public health requirement affecting microbiological safety and nutritional adequacy applicable in the country in which the food is sold should be observed.

4. TECHNOLOGICAL REQUIREMENTS

4.1. Conditions for Irradiation

The irradiation of food is justified only when it fulfils a technological need or where it serves a food hygiene purpose (3) and should not be used as a substitute for good manufacturing practices.

4.2. Food Quality and Packaging Requirements

The doses applied shall be commensurate with the technological and public health purposes to be achieved and shall be in accordance with good radiation processing practice. Foods to be irradiated and their packaging materials shall be of suitable quality, acceptable hygienic condition and appropriate for this purpose and shall be handled, before and after irradiation, according to good manufacturing practices taking into account the particular requirements of the technology of the process.

(3) See note on page 4.

5.1 RE-IRRADIATION

5.1. Except for foods with low moisture content (cereals, pulses, dehydrated foods and other such commodities) irradiated for the purpose of controlling insect reinfestation, foods irradiated in accordance with sections 2 and 4 of this standard shall not be re-irradiated.

5.2. For the purpose of this standard food is not considered as having been re-irradiated when: (a) the food prepared from materials which have been irradiated at low dose levels e.g. about 1 kGy, is irradiated for another technological purpose; (b) the food, containing less than 5 % of irradiated ingredient, is irradiated, or when (c) the full dose of ionizing radiation required to achieve the desired effect is applied to the food in more than one instalment as part of processing for a specific technological purpose.

5.3. The cumulative overall average dose absorbed should not exceed 10 kGy as a result of re-irradiation.

6. LABELLING

6.1. Inventory Control

For irradiated foods, whether prepackaged or not, the relevant shipping documents shall give appropriate information to identify the registered facility which has irradiated the food, the date(s) of treatment and lot identification.

6.2. Prepackaged foods intended for direct consumption

The labelling of prepackaged irradiated foods shall be in accordance with the relevant provisions of the Codex General Standard for the Labelling of Prepackaged Foods (4).

6.3. Foods in bulk containers

The declaration of the fact or irradiation shall be made clear on the relevant shipping documents.

(4) See note on page 4.

(1) For measurement and calculation of overall average dose absorbed see Annex A of the Recommended International Code of Practice for the Operation of Radiation Facilities used for Treatment of Foods (CAC/RCP 19-1979, Rev. 1).

(2) The wholesomeness of foods, irradiated so as to have absorbed an overall average dose of up to 10 kGy, is not impaired. In this context the term "wholesomeness" refers to safety for consumption of irradiated foods from the toxicological point of view. The irradiation of foods up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems (Wholesomeness of Irradiated Foods, Report of a Joint FAO/IAEA/WHO Expert Committee, Technical Report Series 659, WHO, Geneva, 1981).

(3) The utility of the irradiation process has been demonstrated for a number of food items listed in Annex B to the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods.

(4) Under revision by the Codex Committee on Food Labelling.

RECOMMENDED INTERNATIONAL CODE OF PRACTICE FOR THE OPERATION OF IRRADIATION FACILITIES USED FOR THE TREATMENT OF FOODS (*)

1. INTRODUCTION

This code refers to the operation of irradiation facilities based on the use of either a radionuclide source (^{60}Co or ^{137}Cs) or X-rays and electrons generated from machine sources. The irradiation facility may be of two designs, either "continuous" or "batch" type. Control of the food irradiation process in all types of facility involves the use of accepted methods of measuring the absorbed radiation dose and of the monitoring of the physical parameters of the process. The operation of these facilities for the irradiation of food must comply with the Codex recommendations on food hygiene.

2. IRRADIATION PLANTS

2.1. Parameters

For all types of facility the doses absorbed by the product depend on the radiation parameter, the dwell time or the transportation speed of the product, and the bulk density of the material to be irradiated. Source-product geometry, especially distance of the product from the source and measures to increase the efficiency of radiation utilization, will influence the absorbed dose and the homogeneity of dose distribution.

2.1.1. Radionuclide sources

Radionuclides used for food irradiation emit photons of characteristic energies. The statement of the source material completely determines the penetration of the emitted radiation. The source activity is measured in Becquerel (Bq) and should be stated by the supplying organisation. The actual activity of the source (as well as any return or replenishment of radionuclide material) shall be recorded. The recorded activity should take into account the natural decay rate of the source and should be

(*) Revised version of the Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods (CAC/RCP 19-1979).

accompanied by a record of the date of measurement or recalculation. Radionuclide irradiators will usually have a well separated and shielded depository for the source elements and a treatment area which can be entered when the source is in the safe position. There should be a positive indication of the correct operational and of the correct safe position of the source which should be interlocked with the product movement system.

2.1.2. Machine sources

A beam of electrons generated by a suitable accelerator, or after being converted to X-rays, can be used. The penetration of the radiation is governed by the energy of the electrons. Average beam power shall be adequately recorded. There should be a positive indication of the correct setting of all machine parameters which should be interlocked with the product movement system. Usually a beam scanner or a scattering device (e.g. the converting target) is incorporated in a machine source to obtain an even distribution of the radiation over the surface of the product. The product movement, the width and speed of the scan and the beam pulse frequency (if applicable) should be adjusted to ensure a uniform surface dose.

2.2. Dosimetry and Process Control

Prior to the irradiation of any foodstuff certain dosimetry measurements (1) should be made, which demonstrate that the process will satisfy the regulatory requirements. Various techniques for dosimetry pertinent to radionuclide and machine sources are available for measuring absorbed dose in a quantitative manner (2).

Dosimetry commissioning measurements should be made for each new food, irradiation process and whenever modifications are made to source strength or type and to the source product geometry.

Routine dosimetry should be made during operation and records kept of such measurement. In addition, regular measurements of facility parameters governing the process,

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(1) See Annex A to this Code.

(2) Detailed in the Manual of Food Irradiation Dosimetry, IAEA, Vienna, 1977, Technical Report Series No. 178.

such as transportation speed, dwell time, source exposure time, machine beam parameters, can be made during the facility operation. The records of these measurements can be used as supporting evidence that the process satisfies the regulatory requirements.

3. GOOD RADIATION PROCESSING PRACTICE

Facility design should attempt to optimalize the dose uniformity ratio, to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g. for the treatment of frozen food) and also control of the atmosphere. It is also often necessary to minimize mechanical damage to the product during transportation irradiation and storage, and desirable to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

4. PRODUCT AND INVENTORY CONTROL

4.1. The incoming product should be physically separated from the outgoing irradiated products.

4.2. Where appropriate, a visual colour change radiation indicator should be affixed to each product pack for ready identification of irradiated and non-irradiated products.

4.3. Records should be kept in the facility record book which show the nature and kind of the product being treated, its identifying marks if packed or, if not, the shipping details, its bulk density, the type of source or electron machine, the dosimetry, the dosimeters used and details of their calibration, and the date of treatment.

4.4. All products shall be handled, before and after irradiation, according to accepted good manufacturing practices taking into account the particular requirements of the technology of the process (3). Suitable facilities for refrigerated storage may be required.

(3) See Annex B to this Code.

ANNEX A

DOSIMETRY

1. The overall average absorbed dose

It can be assumed for the purpose of the determination of the wholesomeness of food treated with an overall average dose of 10 kGy or less, that all radiation chemical effects in that particular dose range are proportional to dose.

The overall average dose, $\bar{D}$, is defined by the following integral over the total volume of the goods

$$\bar{D} = \frac{1}{M} \int \rho\,(x, y, z) \cdot d\,(x, y. z) \cdot dV$$

where

M	=	the total mass of the treated sample
ρ	=	the local density at the point (x, y, z)
d	=	the local absorbed dose at the point (x, y, z)
dV	=	dx dy dz the infinitesimal volume element which in real cases is represented by the volume fractions.

The overall average absorbed dose can be determined directly for homogeneous products or for bulk goods of homogeneous bulk density by distributing an adequate number of dose meters strategically and at random throughout the volume of the goods. From the dose distribution determined in this manner an average can be calculated which is the overall average absorbed dose.

If the shape of the dose distribution curve through the product is well determined the positions of minimum and maximum dose are known. Measurements of the distribution of dose in these two positions in a series of samples of the product can be used to give an estimate of the overall average dose. In some cases the mean value of the average values of the minimum ($\bar{D}$min) and maximum ($\bar{D}$max) dose will be a good estimate of the overall average dose.
i.e. in these cases

$$\text{overall average dose} \approx \frac{\bar{D}\text{max} + \bar{D}\text{min}}{2}$$

2. Effective and limiting dose values

Some effective treatment e.g. the elimination of harmful microorganisms, or a particular shelflife extension, or a disinfestation requires a minimum absorbed dose. For other applications too high an absorbed dose may cause undesirable effects or an impairment of the quality of the product.

The design of the facility and the operational parameters have to take into account minimum and maximum dose values required by the process. In some low dose applications it will be possible within the terms of section 3 on Good Radiation Processing Practice to allow a ratio of maximum to minimum dose of greater than 3.

With regards to the maximum dose value under acceptable wholesomeness considerations and because of the statistical distribution of the dose a mass fraction of product of at least 97.5 % should receive an absorbed dose of less than 15 kGy when the overall average dose is 10 kGy.

3. Routine Dosimetry

Measurements of the dose in a reference position can be made occasionally throughout the process. The association between the dose in the reference position and the overall average dose must be known. These measurements should be used to ensure the correct operation of the process. A recognized and calibrated system of dosimetry should be used.

A complete record of all dosimetry measurements including calibration must be kept.

4. Process Control

In the case of a continuous radionuclide facility it will be possible to make automatically a record of transportation speed or dwell time together with indications of source and product positioning. These measurements can be used to provide a continuous control of the process in support of routine dosimetry measurements.

In a batch operated radionuclide facility automatic recording of source exposure time can be made and a record of product movement and placement can be kept to provide a control of the process in support of routine dosimetry measurements.

In a machine facility a continuous record of beam parameters, e.g. voltage, current, scan speed, scan width, pulse repetition and a record of transportation speed through the beam can be used to provide a continuous control of the process in support of routine dosimetry measurements.

ANNEX B

EXAMPLES OF TECHNOLOGICAL CONDITIONS FOR THE IRRADIATION OF SOME INDIVIDUAL FOOD ITEMS SPECIFICALLY EXAMINED BY THE JOINT FAO/IAEA/WHO EXPERT COMMITTEE

This information is taken from the Reports of the Joint FAO/IAEA/WHO Expert Committees on Food Irradiation (WHO Technical Report Series, 604, 1977 and 659, 1981) and illustrates the utility of the irradiation process. It also describes the technological conditions for achieving the purpose of the irradiation process safely and economically.

1. CHICKEN (Gallus domesticus)

1.1. Purposes of the Process

The purposes of irradiating chicken are:

(a) to prolong storage life
and/or
(b) to reduce the number of certain pathogenic micro-organisms, such as Salmonella from eviscerated chicken.

1.2. Specific Requirements

Average dose: for (a) and (b), up to 7 kGy

2. COCOA BEANS (Theobroma cacao)

2.1. Purposes of the Process

The purposes of irradiating cocoa beans are:

(a) to control insect infestation in storage
(b) to reduce microbial load of fermented beans with or without heat treatment.

2.2. Specific Requirements

2.2.1. Average dose: for (a) up to 1 kGy
for (b) up to 5 kGy

2.2.2. Prevention of Reinfestation: Cocoa beans whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation and microbial recontamination and spoilage.

3. DATES (Phoenix dactylifera)

3.1. Purpose of the Process
The purpose of irradiating prepackaged dried dates is to control insect infestation during storage.

3.2. Specific Requirements

3.2.1. Average dose: up to 1 kGy

3.2.2. Prevention of Reinfestation: Prepackaged dried dates should be stored under such conditions as will prevent reinfestation.

4. MANGOES (Mangifera indica)

4.1. Purposes of the Process
The purposes of irradiating mangoes are:
(a) to control insect infestation
(b) to improve keeping quality by delaying ripening
(c) to reduce microbial load by combining irradiation and heat treatment.

4.2. Specific Requirements
Average dose: up to 1 kGy

5. ONIONS (Allium cepa)

5.1. Purpose of the Process
The purpose of irradiating onions is to inhibit sprouting during storage.

5.2. Specific Requirement
Average dose: up to 0.15 kGy

6. PAPAYA (Carica papaya L.)

6.1. Purpose of the Process
The purpose of irradiating papaya is to control insect infestation and to improve its keeping quality by delaying ripening.

6.2. Specific Requirements

6.2.1. Average dose: up to 1 kGy

6.2.2. Source of Radiation: The source of radiation should be such as will provide adequate penetration.

7. POTATOES (Solanum tuberosum L.)

7.1. Purpose of the Process
The purpose of irradiating potatoes is to inhibit sprouting during storage.

7.2. Specific Requirement
Average dose: up to 0.15 kGy

8. PULSES

8.1. Purpose of the Process
The purpose of irradiating pulses is to control insect infestation in storage.

8.2. Specific Requirement
Average dose: up to 1 kGy

9. RICE (Oryza species)

9.1. Purpose of the Process
The purpose of irradiating rice is to control insect infestation in storage.

9.2. Specific Requirements

9.2.1. Average dose: up to 1 kGy

9.2.2. Prevention of Reinfestation: Rice, whether prepackaged or handled in bulk, should be stored as far as possible, under such conditions as will prevent reinfestation.

10. SPICES AND CONDIMENTS, DEHYDRATED ONIONS, ONION POWDER

10.1. Purposes of the Process

The purposes of irradiating spices, condiments, dehydrated onions and onion powder are:

(a) to control insect infestation
(b) to reduce microbial load
(c) to reduce the number of pathogenic microorganisms.

10.2. Specific Requirement

Average dose: for (a) up to 1 kGy
for (b) and (c) up to 10 kGy.

11. STRAWBERRY (Fragaria species)

11.1. Purpose of the Process

The purpose of irradiating fresh strawberries is to prolong the storage life by partial elimination of spoilage organisms.

11.2. Specific Requirement

Average dose: up to 3 kGy

12. TELEOST FISH AND FISH PRODUCTS

12.1. Purposes of the Process

The purposes of irradiating teleost fish and fish products are:

(a) to control insect infestation of dried fish during storage and marketing
(b) to reduce microbial load of the packaged or unpackaged fish and fish products
(c) to reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

12.2. Specific Requirements

12.2.1. Average dose: for (a) up to 1 kGy
for (b) and (c) up to 2.2 kGy

12.2.2. Temperature Requirement: During irradiation and storage the fish and fish products referred to in (b) and (c) should be kept at the temperature of melting ice.

13. WHEAT AND GROUND WHEAT PRODUCTS (Triticum species)

13.1. Purpose of the Process

The purpose of irradiating wheat and ground wheat products is to control insect infestation in the stored product.

13.2. Specific Requirements

13.2.1. Average dose: up to 1 kGy

13.2.2. Prevention of Reinfestation: These products, whether prepackaged or handled in bulk, should be stored as far as possible under such conditions as will prevent reinfestation.

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Wholesomeness of irradiated food

Report of a Joint
FAO/IAEA/WHO Expert Committee

Technical Report Series
659

World Health Organization, Geneva 1981

The World Health Organization is a specialized agency of the United Nations with primary responsibility for international health matters and public health. Through this organization, which was created in 1948, the health professions of more than 150 countries exchange their knowledge and experience with the aim of making possible the attainment by all citizens of the world by the year 2000 of a level of health that will permit them to lead a socially and economically productive life.

By means of direct technical cooperation with its Member States, and by stimulating such cooperation among them, WHO promotes the development of comprehensive health services, the prevention and control of diseases, the improvement of environmental conditions, the development of health manpower, the coordination and development of biomedical and health services research, and the planning and implementation of health programmes.

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Further information on many aspects of WHO's work is presented in the Organization's publications.

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This report contains the collective views of an international group of experts and does not necessarily represent the decisions or the stated policy of the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, or the World Health Organization.

Wholesomeness of irradiated food

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Geneva, 27 October - 3 November 1980

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WHOLESOMENESS OF IRRADIATED FOOD

Report of a Joint FAO/IAEA/WHO Expert Committee

A Joint FAO/IAEA/WHO Expert Committee on the Wholesomeness of Irradiated Food met in Geneva from 27 October to 3 November 1980. The meeting was opened by Dr T. Fülop, Director of the Division of Health Manpower Development, on behalf of the Directors-General of the Food and Agriculture Organization of the United Nations, the International Atomic Energy Agency, and the World Health Organization. He mentioned that, as a result of recommendations from previous Joint Expert Committees and of the conclusions of other technical or legal expert consultations organized by these agencies, the FAO/WHO Codex Alimentarius Commission had adopted a general standard for irradiated foods as well as a code of practice relating to food irradiation facilities. Once the recommended general standard is accepted by Governments, foods evaluated by the Expert Committees would be permitted to be irradiated. These would include chickens, papaya, potatoes, strawberries, wheat and ground wheat products, cod and redfish, onions, rice, mangoes, dates, cocoa beans, spices, and pulses. A number of these products are of special interest to developing countries.

1. INTRODUCTION

The world's food requirements continue to grow, but in an environment of scarce resources and of limitations on methods of food production. In addition, the problems of food storage and processing make it necessary to search for effective alternative methods of food preservation, particularly where existing methods are costly because of the energy requirements and may be difficult to provide in some areas. Accordingly, it is reasonable to consider the use of ionizing radiation for food storage and preservation as one alternative, provided that it does not adversely affect the wholesomeness of food.

The need to consider the wholesomeness of food processed by irradiation was emphasized at an international level at a meeting sponsored by FAO, IAEA and WHO in Brussels in 1961 (*1*). The studies required to ascertain the wholesomeness of irradiated food were discussed by a Joint FAO/IAEA/WHO Expert Committee on Irradiated Food in Rome in 1964 (*2*). Taking as a premise that the

irradiation of food resulted in the production of radiolytic products in the food, the Committee adopted the view that these products represented additions to the food. It therefore concluded that the establishment of the safety of irradiated foods should follow procedures similar to those generally used for evaluating the safety of food additives and should be pursued on a food-by-food basis.

A subsequent Joint Expert Committee, which met in 1969 (*3*), had available for consideration the results of a number of toxicological studies carried out on three specific foods on the basis of the recommended procedures. It reviewed the comparative data on several varieties within a major crop, and accepted extrapolation of data from a major variety to all varieties of that crop. The Committee recommended temporary acceptance of irradiated wheat and potatoes as wholesome, and specified further studies on onions. The next Joint Expert Committee, convened in 1976 (*4*), reviewed a large number of animal studies on various irradiated foods. Unconditional or provisional acceptances were recommended for most of them. The Committee also reviewed the results of radiation chemistry studies on the major components of food; it noted that many of the radiolytic products identified were present in food treated by heat and other processes and considered that the health hazard from the concentrations found was probably negligible. It therefore encouraged further studies on the chemical changes in food components associated with irradiation.

A large number of data on irradiated foods and food components have since been generated. The present Committee was convened to evaluate the wholesomeness of the irradiated foods for which data were available. It was also asked to review the acceptability of irradiated food in general, in the light of all the toxicological data and the data from radiation chemistry studies, and to make suggestions for further studies where desirable.

2. GENERAL CONSIDERATIONS

2.1. Principles

The principles and guidelines set out in the reports of the 1964, 1969, and 1976 Joint FAO/IAEA/WHO Expert Committees formed the basis for the present Committee's approach to its consideration of the wholesomeness of irradiated food.

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2.2. Reasons for the use of food irradiation

The Committee was aware that irradiation of food may be used to achieve a variety of desirable objectives including the following, which are classified according to the average radiation dose required to achieve the objectives in question:

Low-dose applications (up to about 1 kGy)
Inhibition of sprouting
Insect disinfestation
Delay of ripening

Medium-dose applications (about 1–10 kGy)
Reduction of microbial load
Reduction in the number of non-sporing pathogenic microorganisms
Improvement in technological properties of food

High-dose applications (about 10–50 kGy)
Sterilization for commercial purposes
Elimination of viruses

The sections that follow (3–7) summarize the evidence which enabled the Committee to assess the effect of the irradiation process on the wholesomeness of food and to arrive at conclusions on the acceptability of irradiated foods.

3. TECHNICAL ASPECTS

3.1 Radiation sources

The Committee stressed the importance of using appropriate radiation sources. From the point of view of safety, the energy level of the radiation applied to food is the most important characteristic that has to be regulated in order to prevent the possible formation of induced radioactivity in the irradiated material. In practice, this is only of importance when considering machine sources, since the most commonly used isotopic sources (^{60}Co and ^{137}Cs) emit radiation of a maximum energy ($\leqq$ 1.33 MeV) which is lower than that causing induced radioactivity. The Committee examined a recent unpublished report (*5*) showing that, with machine sources, induced activity is negligible and very short-lived below an energy level as high as 16 MeV. In this respect the Committee reconsidered and endorsed a

statement (in the report of a Joint FAO/IAEA Advisory Group on International Acceptance of Irradiated Foods (*6*)) that the radiation permitted for food irradiation should have a maximum energy level of (*a*) 10 MeV for electrons and (*b*) 5 MeV for gamma rays and X-rays. On the basis of that statement and the report of the Expert Committee that met in 1964, which indicated X-rays as a suitable type of radiation, the present Committee decided to recommend the inclusion of X-ray sources in the list of acceptable radiation sources.

3.2 Absorbed dose

The present Committee reiterated the view of the Expert Committee of 1976 (*4*) that, as a matter of principle, the applied dose of ionizing radiation should not be higher or lower than is needed to achieve the desired effect. Finding and applying the appropriate dose level is the key to the technologically and economically proper application of the irradiation process to food.

It was stressed that the application of the correct dose would be taken care of, wherever there was good irradiation practice. It was recognized that advice on the doses necessary for the treatment of specific food items and the procedures involved would assist those concerned. Such advice could be included in a code of technological practice.

The Committee noted that no new method for the determination of absorbed dose in the food itself, or indeed for the identification of irradiated food, had become available since 1976. It therefore upheld the view of the Expert Committee that met in 1976 (*4*) that effective dose control can only be exercised in the irradiation plant. The operation of irradiation facilities should be subject to supervision by the appropriate national authorities in order to ensure that proper dose control is exercised. In this respect it was noted that assistance in the calibration of dose control is offered by the IAEA through its programme on High- and Low-Dose standardization and inter-comparison for industrial radiation processing.

As regards setting an overall average dose[1] for the process of irradiation, it was considered that, contrary to the opinion expressed

[1] The overall average dose is the arithmetic mean value of all dosemeter readings in a given irradiation run. To determine this mean value, an adequate number of dosemeters must be randomly distributed in the food as it is exposed to the radiation. The number of dosemeters is considered adequate if it permits estimation of the dose distribution in each portion of the food material of different density and if the measurements are representative for all dose and density fluctuations during a usual run.

by the Expert Committee that met in 1976 (*4*), it is practical (for reasons such as the technical design of the irradiation facility) to stipulate an *average* value rather than to require that no part of the food shall receive less than a minimum, or more than a maximum, dose. Taking into account the ratio of maximum to minimum dose absorbed by the product (i.e., the "dose uniformity ratio") in pilot and currently used commercial facilities, the overall average dose may result in a small fraction of the food receiving a maximum absorbed dose up to 50% higher.

3.3 Processing conditions for irradiation

It is expected that, with wider application of food irradiation, processing conditions will be designed to meet specific technological requirements. Plant design should attempt to minimize the dose uniformity ratio to ensure appropriate dose rates and, where necessary, to permit temperature control during irradiation (e.g., for the treatment of frozen foods) and also control of the atmosphere. It is also necessary to minimize mechanical damage to the product during transportation, irradiation, and storage, as well as to ensure the maximum efficiency in the use of the irradiator. Where the food to be irradiated is subject to special standards for hygiene or temperature control, the facility must permit compliance with these standards.

3.4. Packaging of irradiated food

The packaging method and the packaging material used must be safe and appropriate to the food to be irradiated. Irradiation must not adversely affect the functional properties of the material chosen, nor must it render the material unsafe as determined by appropriate test methods of the kind applied to the unirradiated material.

3.5 Repeated irradiation

While adhering to the view that irradiation of food should normally be carried out once only in each case, the Committee agreed that in certain circumstances repeated irradiation might be justified. This is a departure from the statement in the report of the Expert Committee that met in 1976 that any repetition of irradiation is to be avoided. In deciding upon this change, the present Committee took account of the following findings: (*a*) the concentration of radiolytic products is

a linear function of dose; (*b*) there is a considerable and rapid reduction in the concentration of some of these radiolytic products following irradiation; and (*c*) an overall average dose based on toxicological and other considerations could now be established (see section 10). Consequently, a repetition of irradiation within this overall average dose would not be harmful, provided that no significant impairment of nutritional or technological properties occurred. The Committee agreed that, at the present stage of knowledge, the acceptability of repeated irradiation should be limited to the case of food commodities of low moisture content, in which reinfestation by insects could not be effectively prevented under practical conditions of storage and transport.

Two other types of repetition of the irradiation process were also considered acceptable: (*a*) when the food to be irradiated is a processed form of food that has already undergone low-dose treatment (for example, dried onion prepared from onions treated to inhibit sprouting); (*b*) when it includes irradiated minor ingredients (for example, meat products or dehydrated soup containing irradiated spices). In both cases, it was considered that the additional amounts of radiolytic compounds formed in the final products would be insignificant.

By analogy with tyndallization, fractionated irradiation (i.e., when the full dose has to be applied in two or more instalments) should not be considered as repeated irradiation.

3.6 Technological efficacy

The Committee stressed that, like other food processing techniques, food irradiation is justified only if it serves a useful purpose. Results of studies on the efficacy of the irradiation of the food items specifically examined by the present Committee clearly showed that the applications in question are technologically justified and effective.

3.7 Requirements of quality assurance and labelling

The use of sound raw materials and proper handling and processing techniques, as well as strict maintenance of the wholesomeness and other desirable qualities of foods are a necessity when irradiation or any other form of processing is applied. Furthermore, users and consumers are entitled to expect that the quality and safety of food is not adversely changed either by irradiation or by other currently accepted forms of treatment.

The Committee understood that irradiated foods would be subject to regulations covering foods generally, and to any specific food standards relating to individual foods. It was therefore not thought necessary on scientific grounds to envisage special requirements for the quality, wholesomeness, and labelling of irradiated foods.

4. ASPECTS OF RADIATION CHEMISTRY

4.1 Chemical analysis and wholesomeness evaluation

Treatment of foods with electrons (of energies up to 10 MeV) or gamma-rays and X-rays (of energies up to 5 MeV) does not produce radioactivity in the foods so treated. The need for toxicological evaluation of irradiated foodstuffs stems from the fact that the application of radiation energy results in chemical changes. The nature of the radiation-induced compounds depends primarily on the chemical composition of the food. The concentration of radiation-induced compounds generally increases with increasing radiation dose, but can be modified by factors during irradiation such as temperature, presence or absence of air, and the water content of the sample. The energy taken up by the irradiated food is much less than that taken up by heated foods. It is therefore not surprising that chemical changes caused by irradiation are quantitatively much smaller than those caused by heating. For instance, an absorbed dose of 10 kGy (1 Mrad) corresponds to a temperature rise of only 2.4 °C in a food having the heat capacity of water (4.184 J/°C; 1 cal_{th}/°C). This is about 3% of the energy needed for raising the temperature of water from about 20 °C to 100 °C.

The Expert Committee that met in 1976 concluded that the radiolytic products detected in the wide range of foods and individual food constituents that had been studied did not appear to pose any toxicological hazards in the concentrations at which they were detected. That Committee also accepted that, for doses below 10 kGy (1 Mrad), data may be extrapolated from one member of a food class to related members (p. 10 in that Committee's report (*4*)) and, furthermore, that if certain studies in radiation chemistry and toxicology were continued, a purely chemical approach to the wholesomeness evaluation of irradiated food may prove to be possible (p. 11 in the report (*4*)).

4.2 Recent studies

The above proposals stimulated a great deal of chemical research on irradiated foods and on model systems, which has confirmed the earlier assumptions and enabled more radiolytic products to be identified and quantitatively determined. Thus, the mechanisms of radiation chemical reactions in carbohydrates, lipids and proteins are now known in greater detail.

A study of the radiolytic products in beef, pork, ham and chicken has shown that formation of volatile hydrocarbons depends on the fat content of the meat, regardless of origin. The electron spin resonance spectra from the four types of meat irradiated at −40 °C were identical, indicating the production of common free radical intermediates (I. A. Taub & C. Merritt, unpublished observations).

Another study showed radiolytic products from various starches (derived from maize, amylomaize, waxy maize, wheat, manioc, potatoes, rice, and beans) to be qualitatively identical. Small quantitative differences were related to known properties of these starches, such as the ratio of amylose to amylopectin. These results were confirmed by electron spin resonance which showed that the nature of the radical intermediates is the same in all the irradiated starches (J. Raffi & L. Saint-Lèbe, unpublished observations).

A study of radiation-induced changes in a fruit model has shown that the extent to which these changes take place is in accord with well established kinetic laws. These changes may be calculated using digital computer methods to solve the differential equations which describe the reaction probabilities. Chemical analysis confirmed the prediction that the radiolytic products present in greatest yield in the irradiated fruit were derived from the major constituents of the fruit, i.e., from sugars. Yields of products derived from minor constituents such as protein, malic acid, phenolics, and nicotinamide were much lower (R. A. Basson and co-workers, unpublished observations).

The products of radiolysis in beef (irradiated with an average dose of 56 kGy (5.6 Mrad) at −30 °C ± 10 °C) have been studied in detail. Over 100 volatile compounds have been identified at concentrations varying from 1 to 700 µg/kg, with a total yield of 9 mg/kg. Most of the compounds are known to occur also in unirradiated foods. The Committee noted that this subject had been reviewed recently (*7*, *8*) and agreed that there were no grounds for suspecting these products of being a hazard to the consumer.

4.3 Conclusions

Since similar radiolytic reactions occur with the same constituents of different foods (protein, fat, carbohydrates, water, etc.), common radiolytic products are formed in roughly predictable yields when these foods are irradiated. Although only approximate predictions of product yields are possible at present, these are sufficiently accurate to enable estimates to be made of the upper limits of yields. Thus there is now considerable additional evidence to support the view that information obtained from toxicity tests on one irradiated food can be extrapolated to other foods of similar chemical composition, or to other processing conditions for the same food.

5. NUTRITIONAL ASPECTS

None of the evidence published since 1976 necessitates a change in the advice on the nutritional aspects of irradiated food given by the Joint Expert Committee that met in that year (*4*). The salient points are as follows:

Evidence from most studies suggests that in the low-dose range (up to 1 kGy) used for the irradiation of food, nutrient losses are insignificant. In the medium-dose range (1–10 kGy), losses of some vitamins may occur, if air is not excluded during irradiation and storage. In the high-dose range (10–50 kGy), the technology used to avoid effects on organoleptic quality (i.e., irradiation at temperatures below freezing and in the absence of air) also partially protects nutrients, so that losses may actually be lower than in the medium-dose range if such precautions have not been taken.

Conflicting results have been reported concerning the effect of radiation on vitamin C levels in foods. Some authors have determined only ascorbic acid, without taking into consideration that radiation converts some of this acid to dehydro-ascorbic acid, which is also biologically active. In future studies, both ascorbic and dehydro-ascorbic acid should therefore be determined.

The extent of losses of nutrients due to the irradiation of foods depends on many factors, such as the composition of the food, the radiation dose, the temperature, and the presence or absence of air during irradiation and storage.

Whether or not the loss of a nutrient in an irradiated food is of importance depends on circumstances, such as the contribution that

this food makes to the total diet. For instance, a partial loss of thiamine in fish would be of concern if that was the key source of thiamine to a particular population. Other relevant factors include the nutritional status and requirements of the population for which that food is intended. Some other areas of uncertainty (i.e., folic acid losses) require further investigation.

In 1976 the Joint Expert Committee suggested that the reduction of nutritional value produced by irradiation alone should be compared with that produced by other processes and during storage, and by combinations of irradiation with other processes (*4*). A considerable body of evidence is now available in this regard and the results give no cause for particular concern.

6. MICROBIOLOGICAL ASPECTS

The microbiological safety achieved by the food irradiation process is fully comparable with that of other currently accepted food treatments. No findings have been published during the past four years which would necessitate a reconsideration of the views expressed by the Joint Expert Committee in 1976 (*4*) regarding the microbiological implications of irradiation of food. The results of theoretical and practical work carried out since 1976 have not revealed any new microbiological problems besides those already reviewed.

The results of both field and "inoculated pack" studies have shown that the microbiological safety evaluation of a specific irradiated food can be based only on studies that have specifically been designed to reflect all the circumstances encountered in commercial irradiation. Furthermore, it is important that the hygienic aspects of each individual commodity should be examined separately and that the post-irradiation storage conditions should be carefully and adequately designed to control microbial growth.

6.1 Variations in radiation resistance

The natural radiation resistance of microorganisms and the consequences of their possible survival after irradiation have been reinvestigated with regard to some highly radiation-resistant microorganisms. No new health hazards arising from these organisms have been identified.

Additional experience has also been gained in the application of potentially useful and technologically acceptable combined treatments. For example, it has been demonstrated that the use of irradiation, in conjunction with heat and/or salt treatment, achieves a more efficient reduction in the number of organisms, especially the highly radiation-resistant organisms.

6.2 Radiation-induced genetic variations

Since 1976 there have been no reports to justify the concern, expressed before that time, about the development of irradiation-induced mutations under good operating conditions. As already stated in 1976 (*4*), the risk of inducing greater radiation resistance has only been shown under laboratory conditions.

Changes of taxonomically relevant characteristics, due to mutation, have not been observed under practical conditions of food irradiation and thus do not pose specific problems. Methods for the isolation and enumeration of damaged cells from heated or dried foods may be used for these purposes in the examination of irradiated food, but their applicability should be tested in each case.

No evidence has been reported of enhanced irradiation-induced pathogenicity of foodborne microorganisms, or of increased toxin formation, or induction of antibiotic resistance in irradiated bacteria. Accordingly, the Committee continues to hold the opinion expressed in 1976 that irradiation of food does not increase the pathogenicity of bacteria, yeasts and viruses.

Because of the intrinsic genetic variability of moulds, experimental results should be interpreted with caution. Laboratory experiments, carried out under conditions which differed greatly from those occurring in practice, have shown that mycotoxin production by moulds derived from irradiated spores may vary (in either direction) in comparison with the parent non-irradiated strain. Other laboratory experiments have shown increased mycotoxin production only if heavy inocula are incubated in irradiated, autoclaved moistened foods. These observations have no relevance to food irradiation under present conditions of practice, in which increased formation of mycotoxins has not been found (see section 8.3).

6.3 Microbiological aims of food irradiation

It has been demonstrated that irradiation can reduce the microbial load of a food, thereby increasing the useful life of a perishable food product. The efficacy of irradiation of spices for reducing microbial

load is well documented and this process may be a useful alternative to fumigation treatment. Laboratory animal diets have been irradiated successfully for a number of years on a large scale to render them commercially sterile. *Salmonella* occurs in livestock and is derived from feed and other sources. Since the incidence of such *Salmonella* can be reduced by irradiation of the feed, this process may afford a means of controlling *Salmonella* in poultry and some egg products and of dealing with this common public health problem in many parts of the world. The on-shore irradiation of fish and seafood has received much attention because, among other reasons, *Vibrio parahaemolyticus* is one of the most important foodborne disease agents in warmer climates.

In all, properly designed irradiation processes have been shown to be capable of achieving their intended microbiological objectives (e.g., commercial sterilization, destruction of pathogens). Problems of a microbiological nature that had before been thought might exist have not materialized. Nevertheless, in the case of irradiation, as in any other method of food processing, the gains in microbiological quality must be safeguarded by proper care of the product after processing.

7. TOXICOLOGICAL ASPECTS

7.1 Re-evaluation of provisional acceptances and new evaluations

The Committee reviewed data on fish, onions and rice for re-evaluation and on cocoa beans, dates, mangoes, pulses, and spices and condiments for evaluation. These data were developed in accordance with the guidelines set out in earlier reports of previous Joint Expert Committees. In making its evaluations the Committee used the principles and categories of acceptance, as set out in the previous report (*4*).

The Committee noted that, in the case of cocoa beans, onions, and spices, the presence of natural constituents exerted toxicologically significant effects when these commodities were fed at high levels in the test diet. These effects were found, whether or not the food had been irradiated. The information available on irradiated vegetables was insufficient to make an evaluation, using the principles previously

established. The data on all these commodities were also used in considering the acceptance of irradiated food in general (see section 10).

7.2 Considerations arising from a review of data on irradiated laboratory animal diets and other diets

Concern was expressed by the 1976 Joint Expert Committee about the increasingly common practice of using irradiated prepared feeds for laboratory animals, because of the possible effect on control groups used in toxicological testing (*4*). Data requested on animal colonies reared on irradiated diets were made available to the present Committee, as summarized below.

Studies comparing diets (sterilized by autoclaving or irradiation at 25–44 kGy or treated to eliminate pathogens at 15 kGy) have been published by institutes in Austria, Denmark, France, Hungary, the Netherlands, and the United Kingdom. These included multigeneration studies in rats (*9–14*), mice (*15–17*), and pigs (*18*). In two of the studies (*10, 13*), some of the parent and F_1 generation animals were kept for the whole lifespan for information on carcinogenicity. The numbers of animals examined ranged from 5000 to 500 000.

The Committee concluded from these data that the rearing of test animals on laboratory diets sterilized by irradiation at doses of 15 to 45 kGy was unlikely to obscure any differences if a non-irradiated, hygienically acceptable feed had been used.

The Committee also reviewed information on the results of feeding commercial livestock on feedstuffs irradiated at doses of the order of 8 kGy to reduce organisms belonging to the Enterobacteriaceae, especially *Salmonella*. Breeding and performance studies in poultry (*19*), and pigs (*20, 21*) produced no evidence to show that feeding of irradiated diet to commercial livestock had any adverse effects.

The Committee was aware of the practice of using totally irradiated diets for maintaining patients on immunosuppressive therapy as the only practical means of supplying palatable food under these conditions. No published systematic investigations or accounts were available to the Committee for evaluation. The absence of reports of adverse effects suggests that this practice is not deleterious, and this fact was taken into account in the general assessment of the toxicological acceptability of irradiated food. The Committee recommended that if possible there should be a systematic collection and review of information relating to the use of radiation-sterilized human diets.

7.3 Toxicological evaluation of radiolytic products

The Committee reviewed a study in which the principal radiolytic products from irradiated polysaccharides were fed to rats for 6 months at 1700 times the concentration found after irradiation at 3 kGy. No toxic effects were noted (*22*). These data also support the conclusion set out in section 10 (See also section 4.2).

8. RE-EVALUATION OF FISH, ONION, AND RICE[1]

8.1 Teleost fish and fish products

Purpose of irradiation

(*a*) To control insect infestation of dried fish during storage and marketing.

(*b*) To reduce the microbial load of the packaged or unpackaged fish and fish products.

(*c*) To reduce the number of certain pathogenic microorganisms in packaged or unpackaged fish and fish products.

Average dose

For (*a*) up to 1 kGy, and for (*b*) and (*c*) up to 2.2 kGy.

Temperature requirement

During irradiation and storage the fish and fish products referred to in (*b*) and (*c*) should be kept at the temperature of melting ice.

Microbiological aspects

Vibrio parahaemolyticus is the agent, infectious for man, that is most typically associated with fish and other seafoods. However, infectious agents derived from the intestines of man or other warm-

[1] Summaries of the data used in the evaluations and the references are given in a separate document entitled "Wholesomeness of irradiated food. Summaries of data considered by the Joint FAO/IAEA/WHO Expert Committee, Geneva, 27 October to 3 November 1980". Copies of this document are available, on request, from Division of Environmental Health, World Health Organization, 1211 Geneva 27, Switzerland.

blooded animals may be present in fish because these agents were present in the water in which the fish grew or, as sometimes happens, because they were present in the only water that was available for cleaning fishing equipment (including holding compartments on the ship) or the catch. In addition to infectious agents, toxigenic, spore-forming bacteria such as *Clostridium botulinum* type E may well be present in the fish as caught.

No microbiological problems are likely to arise from irradiation for purpose (*a*). *V. parahaemolyticus* will be eliminated in the product by the doses recommended for purposes (*b*) and (*c*), while the levels of other pathogens and spoilage agents will at least be reduced. Irradiation that does not exceed 2.2 kGy (average dose) is expected to leave enough spoilage organisms to render the food unacceptable before cells derived from surviving *C. botulinum* spores can produce enough toxin to constitute a hazard. However, maintenance of the temperature of melting ice throughout the period of storage of the product has been specified as an additional safeguard against botulism; salting, drying, or other effective measures would have to be substituted if this temperature could not be maintained reliably.

Nutritional aspects

More recent studies have shown that after irradiation at 3 kGy, about 15% of thiamine and 25% of pyridoxine is lost, while riboflavin, niacin and vitamin B_{12} remain unaffected. Higher doses confirmed the particular sensitivity of thiamine and pyridoxine to destruction, the other B complex vitamins remaining practically unaffected. Further studies have confirmed the stability to irradiation of the amino-acid content, particularly of tryptophan. The protein quality of mackerel and hake remained unaltered even by doses of the order of 5 kGy.

The lipids extracted from salted dried irradiated mackerel showed no evidence of adverse nutritional effects at radiation doses of up to 8 kGy. Irradiation up to a dose of 2.2 kGy does not appreciably change the usefulness of fish as a good dietary source of protein, B vitamins, and iodine.

Toxicological aspects

The Committee noted that the results of the studies (ongoing in 1976) had now become available—i.e., short-term, long-term, reproduction, and dominant lethality studies in mice; a short-term study in

rats, investigating changes in serum alkaline phosphatase levels when rats were fed on mixed eviscerated cod and redfish; and short-term and reproduction studies in rats fed on other fish varieties. These did not reveal any evidence suggesting that the feeding of irradiated fish to these animals caused any deleterious effects.

A large number of other feeding studies in which rats and mice were fed on other varieties of fish and fish products have also been reported since 1976. These consisted of short-term and long-term feeding studies and also reproduction, dominant lethality, and a number of mutagenicity studies. These new toxicological data, taken together with the results of previously evaluated studies on various types of irradiated fish, do not indicate any adverse effects arising from the administration of irradiated fish to test systems.

Evaluation

The previous provisional acceptance for cod and redfish is changed to unconditional acceptance for fish and fish products irradiated for the purpose of disinfestation, reducing the microbial load, and reducing the number of pathogenic organisms, at an average radiation dose of up to 2.2 kGy.

8.2 Onions

Purpose of irradiation

To inhibit sprouting during storage.

Average dose

Up to 0.15 kGy.

Microbiological aspects

No special microbiological problems of public health significance are known to be associated with irradiated onions.

Nutritional aspects

Recent studies have confirmed the previously reported lack of effect of irradiation, with doses of up to 0.15 kGy, on the ascorbic acid content of onions even after 10 months of storage. The content

of reducing sugars increased in irradiated onions to a smaller extent than in untreated onions. No changes occurred in the amino-acid composition.

Toxicological aspects

The requirement of the previous Committee for a multigeneration study in rats, at feeding levels below that causing biological changes due to the biologically active substances that were naturally present, has now been met. In addition, a number of short-term, reproduction, teratogenicity, and dominant lethality studies in rats have now been reported. None of these studies has shown any adverse effects when irradiated onions were incorporated at a 2% level in the diet of rats and mice. Additional corroborative evidence has been obtained from many mutagenicity studies on onions treated (for the prevention of sprouting) with doses of radiation of up to 0.15 kGy and from similar studies on dried onion powder treated with radiation doses of up to 15 kGy.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of onions irradiated, for the purpose of controlling sprouting, at an average dose of up to 0.15 kGy.

8.3 Rice

Purpose of irradiation

To control insect infestation in stored rice.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Rice, whether prepackaged or handled in bulk, should be stored, as far as possible, under such conditions as will prevent reinfestation.

Microbiological aspects

If the moisture content of stored rice is too high, fungi such as *Aspergillus flavus*, which are sometimes toxigenic, may grow. Such moulds cannot grow in rice that is stored in a properly dry condition; however, there has been concern over some results that suggested that irradiation could enhance the toxigenic potential of the moulds. It has been shown that toxin-producing fungi are more susceptible than other fungi to irradiation; that a higher water activity is required for the growth of toxin-producing aspergilli than for that of other aspergilli; and that, even at a high water activity, non-toxin-producing strains of *Aspergillus* overgrow the toxin-producing strains and suppress their formation of toxin. Storage of rice at a sufficiently low level of moisture is critically important; the potential mycotoxin hazard is not enhanced by irradiation under practical conditions.

Nutritional aspects

The loss of thiamine on cooking, noted in the report of the 1976 Joint Expert Committee (*4*), may make any further losses due to irradiation relevant where rice is a staple item of the diet and a major source of thiamine. However, a recent study has shown that irradiation at dose levels up to 0.5 kGy did not alter the content of B vitamins or the amino acid composition.

Toxicological aspects

The Committee noted that the results of the long-term study in rats and the short-term study in monkeys, requested in 1976 (*4*), were now available. These showed that the ingestion of irradiated rice caused no adverse effects on the test animals. Another multigeneration study and a dominant lethality study in mice, as well as cytogenetic investigations of the bone marrow of mice and hamsters that had been fed irradiated rice in their diet, showed no adverse effects. These additional results, taken together with the results of the previously reviewed studies, do not indicate any adverse effects from the ingestion of irradiated rice.

Evaluation

The previous provisional acceptance is changed to unconditional acceptance of rice irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.

9. NEW EVALUATIONS[1]

9.1 Cocoa beans

Purpose of irradiation

(*a*) To control insect infestation in storage.
(*b*) To reduce the microbial load of fermented beans with or without heat treatment.

Average dose

For (*a*) up to 1 kGy, and for (*b*) up to 5 kGy.

Prevention of reinfestation

Cocoa beans, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation and microbial recontamination.

Microbiological aspects

Members of 11 genera of moulds, some of which are toxigenic, have been found to be natural contaminants of the cocoa bean embryo and are a major factor limiting the storage life of the product. Mould growth flourishes at moisture levels exceeding 8%. Irradiation with doses of 0.5 kGy eliminates moulds in young (under 2 months) beans, whereas a dose of 5 kGy eliminates moulds even in older beans. Pretreatment of cocoa beans with heat (100 °C for 10–15 minutes) enhances the radiosensitivity of the moulds they contain.

Nutritional aspects

Beans irradiated with doses in the range of 0.1 to 5 kGy showed no significant differences from unirradiated beans with regard to their content of reducing sugars, total amino acids, total fat, and protein. Analysis of cocoa fat in the irradiated material showed no detectable chemical difference from that in unirradiated material.

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[1] See footnote 1 on page 20.

Toxicological aspects

The available results of the short-term and reproduction studies in rats do not indicate any adverse effect due to the irradiation treatment of the cocoa beans. Both irradiated and unirradiated cocoa beans depressed growth and reduced the food intake when incorporated at high levels in the diet of test animals. The observed toxic effects of the cocoa bean diet on fetal development and survival are related to the high theobromine content of the diet. This has been confirmed by cross-fostering experiments and specific studies using theobromine alone. A number of mutagenicity studies have shown the absence of any mutagenic potential in irradiated cocoa beans.

Evaluation

Unconditional acceptance of cocoa beans irradiated, for the purpose of controlling insect infestation or of reducing the microbial load, at an average radiation dose of up to 5 kGy.

9.2 Dates

Purpose of irradiation

To control insect infestation in stored dates.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Prepackaged dried dates should be stored under conditions that will prevent reinfestation.

Microbiological aspects

No microbiological objectives are being pursued by irradiation of dried dates and no public health problems of a microbiological nature are envisaged.

Nutritional aspects

Irradiation of dried dates with doses in the range of 0.3 to 5 kGy had no effect on the reducing sugar content and on major carbohydrate components. No malonaldehyde was detected. No effect on the

protein content was discovered. Irradiation of dates with doses of up to 10 kGy induced no appreciable changes in the amino-acid composition.

Toxicological aspects

The available short-term study in rats revealed no adverse effects that could be related to ingestion of irradiated dates. The results of the reproduction study in rats and of many mutagenicity studies, including a study for induction of recessive lethals in *Drosophila*, revealed no adverse effects that could be ascribed to the irradiation treatment.

Evaluation

Unconditional acceptance of dates irradiated, for the purpose of controlling insect infestation, at an average dose of up to 1 kGy.

9.3 Mangoes

Purpose of irradiation

(*a*) To control insect infestation.
(*b*) To improve the keeping quality by delaying ripening.
(*c*) To reduce the microbial load by combining irradiation and heat treatment.

Average dose

Up to 1 kGy.

Microbiological aspects

Microbial species isolated from mangoes do not appear to be a threat to human health. Germination of naturally occurring or experimentally inoculated *Gloeosporium fusarium* and *G. singulata* is reduced by increasing the doses of irradiation, but complete inhibition requires a dose of 4 kGy, which is technologically unacceptable.

Nutritional aspects

Several studies have shown that irradiation at dose levels of up to 2 kGy caused only slight losses in ascorbic acid and carotene, compared with the effects of freezing or heat treatment. The contents of

riboflavin, niacin and thiamine are not affected. The levels of fat, protein, sugar, and minerals remain unaffected by irradiation.

Toxicological aspects

The available investigations included short-term, long-term, multi-generation, and teratogenicity studies in rats as well as a number of mutagenicity studies. The results indicated that the incorporation in the test diets or irradiated mangoes produced no adverse effects.

Evaluation

Unconditional acceptance of mangoes irradiated for the purpose of controlling insect infestation or for delaying ripening or reducing the microbial load at an average radiation dose of up to 1 kGy.

9.4 Pulses

Purpose of irradiation

To control insect infestation in stored pulses.

Average dose

Up to 1 kGy.

Prevention of reinfestation

Pulses, whether prepackaged or handled in bulk, should be stored, as far as possible, under conditions that will prevent reinfestation.

Microbiological aspects

No specific microbiological problems arise with pulses, whether irradiated or not.

Nutritional aspects

Pulses are a major source of dietary protein in certain parts of the world. Any deleterious effects of irradiation on the nutritional quality of these crops would therefore be of importance. Conflicting results

appear in studies of the protein efficiency ratio (PER)[1] and the effects on B-complex vitamins have not been well established for different pulses. These possible effects should receive consideration wherever irradiated pulses are used as staple items of the diet.

Toxicological aspects

The available short-term studies in mice and rats, as well as a reproduction study in rats, did not indicate any adverse effects due to irradiation of several varieties of dried beans and cowpeas. There was a reduction in the growth rate of rats after the ingestion of high dietary levels of both irradiated and unirradiated beans. A number of mutagenicity studies, including a dominant lethality study in mice, did not reveal any mutagenic potential in several varieties of irradiated dried beans.

Evaluation

Unconditional acceptance of pulses irradiated, for controlling insect infestation, at an average radiation dose of up to 1 kGy.

9.5 Spices and condiments[2]

Purpose of irradiation

(*a*) To control insect infestation.
(*b*) To reduce the microbial load.
(*c*) To reduce the number of pathogenic microorganisms.

Average dose

For (*a*) up to 1 kGy, and for (*b*) and (*c*) up to 10 kGy.

Microbiological aspects

Fungal contaminants, some of which are likely to be toxigenic, occur in untreated spices at an average level of 10^4/g. Other agents of possible concern to human health include the food-poisoning species

[1] The protein efficiency ratio is a rough measure of the nutritive value of proteins, obtained by dividing the gain in body mass by the mass of the protein consumed. It is usually measured in young rats, fed on a diet containing 10% protein under standard conditions.

[2] Inclusive of "dehydrated onion" and "onion powder".

Bacillus cereus and *Clostridium perfringens; Salmonella* and *Shigella* have been reported. Aerobic spore-formers and thermophilic bacteria at levels of up to 10^8/g must be dealt with by some means other than heat. Because the majority of the flora are radiosensitive, irradiation doses of 4–5 kGy reduce the total bacterial counts to less than 10^4/g. Commercial sterility can be achieved at doses of 15–20 kGy, depending on the initial microbial load. The flora that survive irradiation have a lower heat and salt tolerance, so that the subsequent heat treatment of products containing the irradiated spices can be reduced.

Nutritional aspects

Irradiation of paprika at temperatures in the range of 0 °C to 22 °C, with doses of 5–50 kGy, and subsequent storage for 6 months had practically no effect on the carotenoid content.

Radiation treatment with 5 and 15 kGy affected the relative concentrations of some fatty acids but not always in a dose-dependent manner. In some spices there is a small reduction in the proportion of some unsaturated fatty acids. Since spices do not contribute significantly to the nutritional quality of food, these changes are of no nutritional significance.

Toxicological aspects

The available reports of feeding studies in rats (including short-term, reproduction, and teratogenicity studies) are less comprehensive in the case of irradiated spices and condiments than for other irradiated foods. Some of the adverse effects observed in the test animals are related to the ingestion of high dietary levels of spices, both irradiated and unirradiated. No untoward effects, attributable to the irradiation treatment, were reported in these studies. The results of several mutagenicity tests revealed the absence of any mutagenic potential. In evaluating the safety of this commodity, the Committee took into consideration the low levels of spices used in the human diet.

Evaluation

Unconditional acceptance of spices irradiated for the purpose of controlling insect infestation, or of reducing the microbial load and the number of pathogenic microorganisms, at an average radiation dose of up to 10 kGy.

10. CONCLUSIONS ON THE ACCEPTABILITY OF IRRADIATED FOOD

10.1 Toxicological acceptability of irradiated food

The Committee, having reviewed new evidence, was able to formulate a recommendation on the acceptability of food irradiated up to an overall average dose of 10 kGy (see sections 2 and 3). This development follows logically from the approaches to the assessment of the wholesomeness of irradiated food adopted in the past by previous Joint Expert Committees, as described in the Introduction. The following considerations led to this development:

(*a*) All the toxicological studies carried out on a large number of individual foods (from almost every type of food commodity) have produced no evidence of adverse effects as a result of irradiation.

(*b*) Radiation chemistry studies have now shown that the radiolytic products of major food components are identical, regardless of the food from which they are derived. Moreover, for major food components, most of these radiolytic products have also been identified in foods subjected to other, accepted types of food processing. Knowledge of the nature and concentration of these radiolytic products indicates that there is no evidence of a toxicological hazard.

(*c*) Supporting evidence is provided by the absence of any adverse effects resulting from the feeding of irradiated diets to laboratory animals, the use of irradiated feeds in livestock production, and the practice of maintaining immunologically incompetent patients on irradiated diets.

The Committee therefore concluded that the irradiation of any food commodity up to an overall average dose of 10 kGy presents no toxicological hazard; hence, toxicological testing of foods so treated is no longer required.

10.2 Microbiological and nutritional acceptability of irradiated food

The Committee considered that the irradiation of food up to an overall average dose of 10 kGy introduces no special nutritional or microbiological problems. However, the Committee emphasized that attention should be given to the significance of any changes in relation to each particular irradiated food and to its role in the diet.

10.3 High-dose irradiation

The Committee recognized that higher doses of radiation were needed for the treatment of certain foods but did not consider the toxicological evaluation and wholesomeness assessment of foods so treated because the available data are insufficient for this purpose. Further studies in this area are therefore needed.

11. FUTURE RESEARCH

The Committee considered that future research is needed in the following areas in order to increase existing knowledge about the effects of irradiation on food and to facilitate future evaluations:

—The technological and economic feasibility of conducting food irradiation on a larger scale and with a wider variety of foods should be established (see section 3).

—Further studies in the area of wholesomeness assessment of certain foods irradiated at higher doses are desirable (see section 10.3).

—If possible, there should be a systematic collection and review of information on the effects of using irradiation-treated human diets (see section 7).

—The conflicting results published on the effect of radiation on the biological value of proteins and B complex vitamins in pulses should be clarified because of their importance as staple foods in many countries (see section 9.4).

—As there is little recent information on the effect of radiation on folic acid, future work should be carried out on representative folate-containing foods, since the diets in some parts of the world have a marginal folic acid content (see section 5).

—Further work on the effects of combination of irradiation with other processes on the nutritional value of foods so treated is desirable (see section 5).

12. RECOMMENDATIONS

The technological and economic feasibility of food irradiation on an industrial scale should be established. A wider variety of foods should also be studied with respect to their suitability for processing

by irradiation. IAEA and FAO should facilitate such studies and collect data for the purpose of making recommendations.

The use of high-dose radiation for the treatment of certain foods has been recognized as being technologically feasible. To assess the safety of this process, further information is needed on its nutritional, microbiological and toxicological implications. Such information is being generated and should be brought together by FAO, IAEA and WHO for future evaluation.

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EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

August 1977

Prepared for

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
DEPARTMENT OF THE ARMY
WASHINGTON, D.C. 20314

under

Contract Number DAMD-17-76-C-6055

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For more than 20 years, the U.S. Army has been investigating ionizing radiation as a possible preservation process for foods. It has developed a practical procedure for the preservation of beef; meat treated in this manner is now undergoing a multigeneration wholesomeness study in mice, rats and dogs. As an adjunct to this feeding study, the Army requested a thorough review of the possible toxicity to man of the volatile compounds detected in the irradiated beef. This is a report of that review. Sixty-five compounds have been

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identified in the irradiated beef. These include both saturated and unsaturated aliphatic compounds containing from 2 to 27 carbon atoms; certain of their alcohol, aldehyde and ketone derivatives; three aromatic hydrocarbons; and some sulfur, nitrogen and chlorine containing compounds. The concentrations of the individual compounds range from 1 to 700 μg per kg beef with a total concentration of 9.4 mg per kg.

The Committee reviewed the usual distribution of each compound in foods, water supplies and the atmosphere as well as its absorption, metabolic formation and disposition, acute and chronic toxicity and potential hazard for man. Virtually all of these compounds are ordinary constituents of human foods; many are approved additives or flavoring agents; and some are widely dispersed in our atmosphere and water supplies. The concentrations of the compounds reported in irradiated beef are within official guidelines, where such exist, while many others are below the amounts found in common foods or absorbed from other sources.

Tetrachloroethylene and benzene were scrutinized with especial care because of their possible carcinogenicity. The available evidence demonstrates that the tetrachloroethylene found in irradiated beef samples was not a radiolytic product, but was a contaminant probably arising from its use as a cleaning agent in the processing plant. Among different samples of beef, it was either not present, or its concentrations were no greater than those in nonirradiated beef. Irradiation with doses up to 120 kilograys (12.0 megarads) did not increase its concentration in the beef. The daily intake from air, water, and other foods is many times greater than that from irradiated beef. Benzene is suspected of being a possible human leukemogen, although many experts dispute this claim. The small contribution from irradiated beef is not believed to constitute a significantly added risk.

On the basis of the available data, the Committee concluded that there were no grounds to suspect that the radiolytic compounds evaluated in this report would constitute any hazard to health to persons consuming reasonable quantities of beef irradiated in the described manner.

Block 19-

ketones
nitrogen-containing compounds
oxygen-containing compounds
sulfur-containing compounds
toxicity

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EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

August 1977

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Bethesda, Maryland 20014

SUMMARY

For more than 20 years, the U.S. Army has been investigating ionizing radiation as a possible preservation process for foods. It has developed a practical procedure for the preservation of beef; meat treated in this manner is now undergoing a multigeneration wholesomeness study in mice, rats and dogs. As an adjunct to this feeding study, the Army requested a thorough review of the possible toxicity to man of the volatile compounds detected in the irradiated beef. This is a report of that review.

Sixty-five compounds have been identified in the irradiated beef. A number of nonvolatile compounds would not be detected by the analytical methods employed and were not considered in this study. Those identified include both saturated and unsaturated aliphatic compounds containing from 2 to 17 carbon atoms; certain of their alcohol, aldehyde and ketone derivatives; three aromatic hydrocarbons; and some sulfur-, nitrogen- and chlorine-containing compounds. The concentrations of the individual compounds range from 1 to 700 μg per kg beef with a total concentration of 9.4 mg per kg.

The Select Committee reviewed the usual distribution of each compound in foods, water supplies and the atmosphere as well as its absorption, metabolic formation and disposition, acute and chronic toxicity and potential hazards for man. Many of these compounds are found in human foods; some are approved additives or flavoring agents; and some are widely dispersed in our atmosphere and water supplies. The concentrations of the compounds reported in irradiated beef are within official guidelines, when such exist, while many others are below the amounts found in common foods or absorbed from other sources.

Tetrachloroethylene and benzene were scrutinized with especial care because of their possible carcinogenicity. The available evidence demonstrates that the tetrachloroethylene found in irradiated beef samples was not a radiolytic product, but was a contaminant probably arising from its use as a cleaning agent in the processing plant. Among different samples of beef, it was either absent, or its concentrations were no greater than those in nonirradiated beef. Irradiation with doses up to 120 kilograys* (12.0 megarads) did not increase its concentration in the beef. The daily intake from air, water and other foods is many times greater than that from

*In this report, absorbed dose is generally expressed in terms of the gray (Gy), as recommended by the International Organization for Standardization. Values expressed in terms of the rad are given in parenthesis. One rad = 10^{-2} Gy. In a few instances where graphs are reproduced from reports published before this convention was adopted, the older terminology is retained.

irradiated beef. Benzene is suspected of being a possible human leukemogen, although many experts dispute this claim. The small contribution to the general environmental burden of benzene from irradiated beef is not believed to constitute a significant added risk.

On the basis of the available data, the Committee concluded that there were no grounds to suspect that the radiolytic compounds evaluated in this report would constitute any hazard to health to persons consuming reasonable quantities of beef irradiated in the described manner.

FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB) provides scientific assessments of topics in the biomedical sciences. Reports are based upon comprehensive literature reviews and the opinions of knowledgeable investigators who are actively engaged in work in specific areas of biology and medicine.

This technical report was prepared for the U. S. Army Medical Research and Development Command by the LSRO, FASEB, in accordance with provisions of contract number DAMD-17-76-C-6055. The report was written by the members of an ad hoc Select Committee on Health Aspects of Irradiated Beef with the assistance of the LSRO staff.

The Select Committee whose members are listed in Section IX accepts the responsibility for the contents of the report. Other scientists provided useful information to the Select Committee; however, the listing of their names does not imply that they endorse the study conclusions. Special appreciation is expressed to Dr. Walter M. Urbain, Special Consultant and to Dr. C. Jelleff Carr, Director Emeritus, LSRO, for their valuable assistance to the Select Committee in the preparation of this report.

The report was approved by the Select Committee, the Director of LSRO, and subsequently by the LSRO Advisory Committee composed of representatives of each constituent society of FASEB, under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures the report was approved and transmitted to the U.S. Army Medical Research and Development Command by the Executive Director, FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of the individual members of its constituent societies.

Kenneth D. Fisher, Ph. D.
Director
Life Sciences Research Office

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I. INTRODUCTION

Although it has long been known that food can be subjected to irradiation and thus preserved for extended periods (1, 2, 5), only irradiated wheat and potatoes are currently accorded official sanction in the United States.

Radiation is defined by current statutes (21 CFR 179.21, formerly 121.3001) as a food additive (3), rather than as a process, so that rigorous standards of safety must be met before food processed by irradiation can be approved for human consumption by the Food and Drug Administration. In 1954, the Surgeon General's Office undertook an extensive program to meet these standards of wholesomeness* for irradiated foods, concentrating on products of special military significance, especially beef, chicken, pork and ham.

After many years of investigation, the Army was ready for a definitive study and called upon governmental and academic scientists to devise an experimental protocol that would determine unequivocally the safety or hazard of foods subjected to sterilizing doses of irradiation. Beef was chosen as the first food to be tested because of its wide consumption in the military and its popularity with the American public. Extensive discussions were held with officials of the FDA and with governmental and academic scientists. A task force was established under the aegis of the National Academy of Sciences - National Research Council to provide overall guidance. As a result, a comprehensive long-term experiment was designed that would evaluate the effect of feeding irradiated beef to several generations of mice, rats and dogs. The animals were to be subjected to a comprehensive toxicological study to uncover any acute or chronic harmful effects of this diet. On March 1, 1971, a contract was awarded to the Industrial Bio-Test Laboratories, Inc. of Northbrook, Illinois to conduct the prescribed study. At the suggestion of the Food and Drug Administration, the Army expanded its wholesomeness assay to include mutagenic and teratogenic effects as well as analysis of heavy metals, pesticide residues and organic volatile compounds.

The Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (FASEB) was asked to undertake an evaluation of the possible toxicity of certain compounds found in irradiated beef. To accomplish this task, the staff of LSRO compiled relevant data on the distribution, metabolism and toxicology of

*With reference to irradiated foods, the term "wholesomeness" is generally used to encompass microbiological, nutritional and toxicological safety (4).

those compounds found in irradiated beef by the Army , LSRO also convened a committee of investigators in biochemistry, pharmacology, oncology, toxicology, food technology and nutrition to review the available data and to assess the health aspects of the compounds separately and in toto. The committee members are listed in Section IX (p. 111).

This report contains the findings and conclusions of this committee.

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*To facilitate referral, the references cited appear at the end of each section rather than in a single bibliography for the entire report. Consequently, some references appear in more than one section.

II. MATERIALS AND METHODS

The chemical analyses which form the basis of this report were performed on samples randomly selected from large batches of beef prepared for the animal-wholesomeness studies.

A. BEEF PREPARATION

Fresh beef was processed by a major packing house in a plant inspected by the U.S. Department of Agriculture (USDA), meeting all USDA requirements. Cleanup was done during the off-shift (usually at night). After cleanup, all equipment was sprayed with food-grade white oil and not rinsed before use, in accordance with the USDA approved procedures.

Cattle, approximately 500 kg live weight, were placed in restraining racks, stunned and hung on rails by their hind legs. They were slaughtered and dressed conventionally. The carcass was split to yield approximately 162 kg per side. These sides were washed with hot- and cold-water sprays and placed for 24 to 72 hours in a chilling room at -3° to 2°C. Refrigeration was of the ammonia type. The water in the plant was chlorinated to meet USDA requirements. The sides of beef were cut into front and hind quarters and transferred to the cutting table by a stainless steel conveyor. The quarters were then deboned, partially defatted and cut into large primal cuts.

For production lots 1, 2, 3 and 4, the meat from all portions of the carcass was cut by hand into 60- to 700-gram pieces. For production lots 5, 6 and 7, the meat was moved by the conveyor to a slicing machine which cut the meat into 2.5-cm strips. The hand-cut or machine-sliced meat was transferred to a meat tub holding 325 kg. When held in these tubs, the meat was always covered with a sheet of plastic. A sample of this meat, removed for chemical analysis, represents the "raw" beef shown in Table 1. The remainder was placed in a 650-kg capacity ribbon vacuum mixing machine and sodium chloride, sodium tripolyphosphate (TPP) and ice were added to the meat in the following proportions.

	Basic ratio kg	Typical batch kg
Deboned meat	100.000	650.000
NaCl	0.750	4.875
TPP	0.375	2.437
Ice	3.000	19.500

The mixer was evacuated to 200 to 250 torr and the meat was mixed with these additives for at least 20 minutes at 3° to 5°C. The mixture was then transferred to meat tubs, kept in coolers at -3° to 2°C for not more than 24 hours, and then loaded into a dumping machine which was a large, funnel-like piece of equipment used to fill the stuffing machine located on the lower floor. The stuffing machine filled casings to fit two types of containers: no. 6½ casings for cans and no. 11 casings for pouches. On the clipping table the filled casings were cut into rolls containing 15 kg for cans and 11.5 kg for pouches.

Thirty of these rolls were placed on each of seven trees (210 rolls) and treated in stainless steel cookhouses which were normally employed as smokehouses. To produce the enzyme-inactivated beef, they were washed before use and smoke was not added. The total elapsed time from the mixer to cookhouse was at least 1, but not more than 24 hours. In the cookhouse, which was heated with hot steam coils, the meat was exposed to gradually increasing air temperatures:

First 3 hours	50° to 60° C
Next 6 hours	60° to 71° C
As required	71° to 90° C

To obtain the desired center temperature of 68° to 75° C and a yield of not more than 85 percent deboned weight of the raw beef, steam was injected to control the humidity of the cookhouse.

Next, the rolls were spray washed with cold water and the trees were transferred from the cookhouse to a cooler (-12° to 1°C) until the center temperature cooled to -3° to 5°C. This temperature must be reached within 12 hours. The rolls were kept in the cooler at -3° to -2°C for up to 8 days if their casings had not been removed. They were then placed in meat tubs and moved to the processing room for canning or pouching at 10°C. Four separate products were processed: frozen controls, thermally processed gamma irradiated and electron irradiated.

Frozen Controls

The rolls were placed on the cutting table, the casings were removed and the meat was cut into 1.3-kg pieces which were packed into spray-washed 404 x 700 cans, evacuated to 600 torr before sealing, packed 12 cans to a case and frozen at -40° to -18°C. The frozen samples were shipped to the feeding site and kept frozen at -20° to -18°C until used.

Thermally Sterilized

The rolls were placed on the cutting table, their casings were removed, the meat was cut into 0.37-kg pieces, and packed into 404 x 202 cans. The cans were evacuated to 600 torr, sealed, placed in retort baskets and thermally processed to F_0 =5.8 (a minimum of 5.8 minutes at 121°C). The cans were labeled and packed 48 cans to the case. Samples were removed, incubated for 20 days at 35.6°C and were inspected for sterility by the USDA. The cases were then shipped to the feeding site and stored at 21° to 25°C until used.

Gamma Irradiated

The rolls were placed on the cutting table, their casings were removed and the meat was cut into 1.3-kg sections. These were packed into 404 x 700 cans which were then evacuated to 600 torr and sealed. Dosimetry labels were placed on the lids, the cans were packed 12 to the case, frozen at -40° to -18°C and shipped to the Natick Laboratories in the frozen state. Here they were stored at -45 to -35°C until irradiated with cobalt at an average dose of 56.0 kGy (5.6 megarads) at -30° ± 10°C, inspected and shipped to the feeding site where they were stored at 21° to 25°C until used.

Electron Irradiated

The rolls were taken from the cages, placed on the cutting table and the casings were removed. The meat was cut into 225-g slices and transferred to meat trays. The slices were packed into flexible pouches and vacuum sealed. Dosimeters were placed on the pouches, which were kept overnight at 1° to 2° C in meat tubs. The pouches were then inspected for vacuum integrity and packed eight pouches per box and eight boxes per case. They were frozen at -40° to -18°C and shipped to Natick, where they were stored at -45° to -25°C until irradiated with an average dose of 56 kGy (5.6 megarads) at -30° ±10°C by a 10 MeV electron linear accelerator. After inspection, the irradiated pouches were shipped to the feeding site, where they were stored at 21° to 25° C until used.

B. ANALYTICAL (1, 2, 3)

All analyses were performed by the Analytical Chemistry Group, Food Sciences Laboratory, U.S. Army Natick Research and Development Command under the direction of Dr. C. Merritt, Jr.

Preparation of Meat Samples

"Uncooked" meat was removed from the container, cut into approximately one-inch cubes, ground through a quarter-inch plate, and mixed well.

"Cooked" samples were prepared to simulate the treatment accorded the beef prior to its consumption in the wholesomeness study. Meat cubes (300-400 g) plus their juices were placed in 2- to $2\frac{1}{2}$-inch thick layers in aluminum foil trays. The meat was covered and heated for 15 minutes in a convection type oven at 204° C. The covers were then removed while heating continued for 2 minutes more. The heated meat and juices were ground and mixed.

Collection of Total Condensate

The coarsely ground sample was weighed to the nearest gram and placed in a cylindrical vacuum bottle of approximately one liter capacity. The flask containing the sample was attached to a vacuum manifold, cooled to -196° C in a liquid nitrogen bath and the system evacuated to an absolute pressure of 1×10^{-3} torr. The volatile compounds were vacuum distilled at 30° ± 5° C. This temperature was maintained by periodically changing the water bath around the flask. The volatiles were collected in a smaller cylindrical sample bottle (approximately 400 ml) immersed in a liquid nitrogen bath. Both the vacuum manifold and the sample bottle had previously been evacuated to an absolute pressure of less than 1×10^{-3} torr. This distillation continued for 6 hours. The condensed distillate in the smaller cylindrical sample bottle represents the total condensate.

Fractionation of the Total Condensate

The total condensate (mostly water) was allowed to thaw. The flask was then immersed in a bath of dry ice and ethanol; in some instances acetone replaced the ethanol. When the sample had reached the temperature of dry ice mixture (about -80° C), the compounds volatile at this temperature were distilled from the total condensate and collected in a second sample bottle immersed in a liquid nitrogen bath. This thawing, freezing and distillation cycle was repeated five times, or until the absolute pressure in the bottle in the dry ice-ethanol bath was less than 5×10^{-3} torr. This process divided the total condensate into two fractions; the water fraction or the residue in the bottle immersed in the dry ice-ethanol bath; and the CO_2 fraction, the distillate collected at -196° C (liquid nitrogen bath).

Extraction and Concentration of the Water Fraction

The water fraction was extracted with three 10 ml portions of diethyl ether. The ether extract was vacuum distilled from a dry ice-ethanol bath. The distillate was condensed in a bottle immersed in a liquid nitrogen bath. The residue from this procedure is the concentrated water fraction.

Analysis of the Volatile Fractions

The fractions were subjected to gas chromatography. A support-coated open tubular (SCOT) column coated with 1, 2, 3 tris (2-cyanoethoxy) propane (TRIS), precooled to -100°C and programmed from -50° to 125° C at 5° C per minute was used for the CO_2 fraction. For the water fraction, a SCOT column coated with carbowax 20M was used, precooled to -50° C and programmed from 0°C to 200° C at 5° C per minute. The effluents flowed directly into the source of a time-of-flight mass spectrometer which allowed the acquisition of both qualitative and quantitative data.

Chloroform Extraction of Beef Residue After Collection of Total Condensate

This procedure has been used thus far only on four beef wholesomeness samples. All four of these samples were from a single procurement.

The beef residue was placed in a Waring blender with 250 ml of chloroform at room temperature. The mixture was blended for 5 minutes, filtered and the residue washed with 30 ml of chloroform. The combined filtrate and wash were placed in a separatory funnel, the residual water was removed and the chloroform was evaporated at 25°C in a rotary evaporator. The flask containing the residue was fitted with a cold finger and attached to a high-vacuum system.

The cold finger was filled with liquid nitrogen and the flask was evacuated. The residue was heated to 80° C with continual magnetic stirring. The distillate was collected on the cold finger for two hours and then washed into a test tube with several small aliquots of chloroform totaling 10-12 ml. The volume of chloroform was reduced to approximately 20 µl by evaporation under a gentle stream of nitrogen gas. The volume of the remainder was measured and a 0.2µl aliquot was analyzed by combined programmed temperature gas chromatography-mass spectrometry. The gas chromatographic

column was a SCOT column coated with carbowax 20M, precooled to 0°C and programmed from 0°C to 200°C at 5°C per minute with a helium carrier gas flow rate of 5 ml per minute.

The sensitivity of the analytical technique is approximately 1 ppb or 1 µg of compound detectable per kg of beef.

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III. RESULTS

Table I is a list of the 65 compounds and their concentrations detected in the cooked and uncooked samples of frozen, thermally sterilized and irradiated beef. The variously processed beef samples on which these analyses were made are aliquots of the batches used in the animal wholesomeness experiment. This use of identically treated beef permits a correlation between the chemical and the feeding studies. The amounts of the individual compounds range from 1 to approximately 700 µg per kg. The hydrocarbons are by far the most abundant, both in their number and their quantities; 70 percent of all the substances and which comprise almost 90 percent of the total weight, fall into this category. The saturated aliphatics (alkanes) predominate. Their content exceeds the combined total of alkenes and alkynes by 1.5 times and of the aromatic hydrocarbons by more than 60 times.

As might be expected, heat causes a significant loss of the volatile components, so the concentrations in the cooked samples are almost always lower than in the uncooked beef. Thus, ethane was found in the uncooked irradiated specimens, but none could be detected in the cooked samples. Methane, an even more volatile hydrocarbon, was absent from both the cooked and uncooked beef fractions, although theoretically, significant quantities should have been produced by irradiation.

The type of radiation, gamma rays by ^{60}Cobalt or high energy electrons by the linear accelerator, does not significantly affect the kind or amount of compounds produced. Consequently, no distinction has been made between these sources in considering the radiolytic products.

The presence of a compound in irradiated beef does not necessarily imply that it is a radiolytic product. With few exceptions, all of the compounds in Table I have been found in other foods, often in concentrations exceeding those in irradiated beef. As is evident from this table, many but not all of the compounds increase significantly after irradiation. Most of the aliphatic hydrocarbons are substantially more abundant in irradiated than in nonirradiated beef. However, the quantities of xylene and tetrachloroethylene are essentially the same whether or not the beef was irradiated, while acetonitrile, carbonyl sulfide, dimethyl disulfide, methanol and methyl heptane are present in greater amounts in the thermally sterilized than in the irradiated samples.

The kind and concentration of the resulting products will be markedly influenced by the fat content of the beef and by irradiation parameters such as dose, temperature and oxygen tension (see Section IV).

Table 1. Compounds identified in beef.

Compound	Cobalt irradiation[a]				Linac irradiation[a]				Thermally sterilized[a]				Frozen control[a]				Raw[a]	
	Cooked		Uncooked		Cooked		Uncooked		Cooked		Uncooked		Cooked		Uncooked			
	ppb	SD	ppb	SD	ppb	SD	ppb	SD	ppb	SD	ppb	SD	ppb	SD	ppb	SD	ppb	SD
Alkanes																		
Ethane	0	-	172	20.2	0	-	175	18.6	0	-	0	-	0	-	0	-	0	-
Propane	60	19.7	164	16.9	65	20.3	173	16.7	0	-	0	-	0	-	0	-	0	-
Butane	125	39.7	208	23.1	127	42.0	221	31.0	0	-	0	-	0	-	0	-	0	-
Pentane	170	54.1	205	21.4	180	52.8	203	49.7	4	1.9	8	2.1	2	0.7	1	0.7	1	-
Hexane	207	69.8	209	23.2	248	59.9	217	24.9	67	24.5	125	32.1	7	1.9	6	1.5	1	-
Heptane	281	96.1	417	43.6	298	88.1	438	50.4	62	16.6	102	25.9	8	2.2	10	1.7	1	1.1
Octane	284	91.2	348	37.4	302	84.9	367	42.2	0	-	47	8.3	0	-	0	-	0	-
Nonane	125[c]	-	266[c]	-	146[c]	-	-	-	0	-	0	-	0	-	0	-	0	-
Decane	175[c]	-	362	278-436[b]	184[c]	-	-	-	0	-	0[d]	-	0	-	0	-	1	0.4
Undecane	217[c]	-	178	108-267[b]	203[c]	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Dodecane	326[c]	-	207	98-317[b]	286[c]	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Tridecane	-	-	321	293-362[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Tetradecane	-	-	313	231-392[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Pentadecane	-	-	696	617-796[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Hexadecene	-	-	221	122-286[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Heptadecane	-	-	394	376-439[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Alkenes																		
Ethene	0	-	28	3.3	0	-	28	3.2	0	-	0	-	0	-	0	-	0	-
Butene	12	5.2	32	3.5	13	4.5	33	3.6	0	-	0	-	0	-	0	-	0	-
Pentene	2	1.0	36	4.5	2	0.9	38	3.6	3	0.8	4	4.4	3	1.0	0	-	0	-
Hexene	2	1.1	34	4.6	2	0.9	35	4.9	22	4.7	31	8.5	1	-	1	-	4	0.7
Heptene	46	14.1	111	13.5	45	15.7	116	14.5	12	5.7	31	8.0	2	0.2	1	-	0	-
Octene	22	8.4	95	11.7	20	7.4	97	10.1	0	-	0	-	0	-	0	-	0	-
Nonene	33[c]	-	59[c]	-	48[c]	-	61	9.1	0	-	0	-	0	-	0	-	0	-
Decene	101[c]	-	126	70-161[b]	116[c]	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Undecene	82[c]	-	78	54-103[b]	93[c]	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Dodecene	171[c]	-	136	113-229[b]	162[c]	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Tridecene	-	-	178	121-268[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Tetradecene	-	-	486	324-588[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Pentadecene	-	-	121	98-187[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Hexadecene	-	-	186	116-234[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Heptadecene	-	-	618	583-803[b]	-	-	-	-	-	-	0[d]	-	-	-	0[d]	-	-	-
Iso-alkanes																		
2-Methyl propane	27	8.1	45	6.9	28	9.2	47	7.4	0	-	9	1.4	0	-	0	-	0	-
2-Methyl butane	4	1.5	19	2.4	5	1.4	22	3.4	0	-	143	46.0	0	-	0	-	1	-
2-Methyl pentane	10	3.4	33	4.3	11	4.1	34	3.1	1	-	28	6.5	1	-	0	-	0	-
2-Methyl heptane	11	4.1	29	39.5	12	4.0	24	3.2	27	10.1	47	10.8	4	1.2	4	1.0	0	-

Iso-alkenes																		
2-Methyl propene	2	0.8	37	4.6	2	0.9	39	5.3	0	-	4	1.0	0	-	0	-	0	-
Alkynes																		
Decyne	25[a]	-	23	18-27[b]	23[a]	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Undecyne	9[c]	-	4	0-6[b]	11[a]	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Dienes																		
Tetradecadiene	-	-	98	83-113[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Pentadecadiene	-	-	73	68-79[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Hexadecadiene	-	-	706	626-839[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Heptadecadiene	-	-	16	12-21[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Aromatic hydrocarbons																		
Benzene	15	5.1	18	2.5	14	5.0	19	2.1	2	-	0	-	3	-	0	-	0	-
Toluene	50	17.9	65	7.1	50	17.1	66	7.4	48	14.5	73	20.5	3	1.6	6	1.5	0	-
Xylene	4	1.9	1	0.2	3	1.2	1	0.5	7	1.4	7	4.7	1	-	1	-	0	-
Alcohols																		
Methanol	16	6.2	20	3.2	15	5.2	19	2.6	23	6.7	40	9.7	41	12.0	0	-	0	-
Ethanol	76	25.7	122	28.3	73	30.3	124	16.2	9	2.9	15	3.9	18	1.0	0	-	0	-
Ketones																		
Acetone	108	31.3	137	14.9	106	32.8	140	14.1	65	20.1	120	28.1	3	1.1	4	1.1	1	0.6
2-Butanone	71	24.3	83	10.0	72	24.7	90	9.3	5	1.6	10	2.5	5	3.3	0	-	0	-
Aldehydes																		
2-Methyl pentanal	11	3.2	10	1.8	10	3.3	11	1.9	0	-	0	-	0	-	0	-	0	-
Undecanal	-	-	76	52-89[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Dodecanal	-	-	63	53-76[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Tetradecanal	-	-	54	47-65[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Pentadecanal	-	-	46	41-52[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Hexadecanal	-	-	127	94-187[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Octadecanal	-	-	30	26-34[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Hexadecenal	-	-	33	27-41[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Octadecenal	-	-	398	371-432[b]	-	-	-	-	-	-	0[c]	-	-	-	0[c]	-	-	-
Sulfur compounds																		
Carbonyl sulfide	2	0.8	2	0.9	2	0.8	2	0.8	22	16.0	75	16.0	0	-	0	-	0	-
Hydrogen sulfide	2	0.8	2	0.6	1	0.6	1	1.7	1	1.4	5	1.3	0	-	0	-	0	-
Ethyl mercaptan	7	2.4	9	3.1	7	2.5	11	2.2	0	-	0	-	0	-	0	-	0	-
Dimethyl sulfide	4	1.3	5	1.5	4	1.4	6	1.4	0	-	0	-	0	-	0	-	0	-
Dimethyl disulfide	3	1.0	4	0.8	3	1.2	4	0.8	7	2.9	13	3.3	1	-	1	-	0	-
Choloro compounds																		
Tetrachloroethylene	9	3.5	8	1.5	9	3.1	8	1.8	9	3.2	11	2.8	10	3.0	12	1.8	4	0.8
Miscellaneous																		
Acetronitrile	3	1.0	1	-	3	0.9	1	-	21	12.7	57	14.2	6	9.1	3	0.7	0	-

[a] see text for treatment
[b] range of 4 determinations
[c] determined for only one sample

ppb = parts per billion
SD = standard deviation
0 = below detectable limits
- = not determined

NOTE: Unless otherwise indicated, figures represent averages of 10 samples for raw beef and approximately 50 samples for other treatments.

In this connection, it must be emphasized that the Committee considered only those compounds detected in the irradiated beef prepared and analysed according to the procedures described in the experimental section (pages 10 to 15). This approach permitted correlation of the Committee's study with the wholesomeness experiments in which the animals were fed beef composed and irradiated in the manner described. It is recognized that variations in the beef composition, the irradiation technique or the analytical procedures may modify these results.

During the course of this study, analytical techniques have been improved to allow determination of certain higher molecular weight compounds not originally reported in the quantitative analysis. This effort to improve the analytical methodology is a continuing project at the Natick laboratories. A recently developed, unpublished procedure utilizing dichloromethane appears to extract certain hydrocarbons more thoroughly than previous techniques. Very preliminary results on a single sample reveal significantly higher levels of pentadecane and heptadecene in the beef than those shown in this report. It is hoped that continued analytical refinements will ultimately ensure a comprehensive and accurate inventory of compounds in irradiated beef. However, at present, the Committee must confine its consideration to the best available data, recognizing both their qualitative and quantitative limitations.

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IV. VARIABLES AFFECTING RADIOLYTIC PRODUCTS

Irradiation produces volatile compounds in meat because the energy absorbed from the electron or gamma source is sufficient to ionize any atom with which it interacts. Interatomic bonds are broken, thus fragmenting the molecules and forming free radicals which can recombine to form new compounds. In most biological systems, water is the most abundant compound and the most obvious target of high energy irradiation. Transitory radiolytic products of water are formed; these react with other molecules or fragments to produce a number of compounds (2). Irradiation may also directly cleave bonds in organic molecules to produce free radicals. The recombination of these molecular fragments creates new compounds. Theoretically, irradiation of a complex matrix such as beef should produce a multitude of different fragments whose combination could result in numerous radiolytic products. In the frozen state, the number of new products would be reduced somewhat since the rigid structure would impede the reaction of molecular fragments. Many of these products would be nonvolatile and would have remained undetected by the analytical methods employed in this study. These compounds were not considered.

A. FAT CONTENT

Investigators have shown the major source of volatile compounds formed upon irradiation of beef to be the lipid fraction (5, 8, 9, 10). Protein is of secondary importance in their production and carbohydrates, vitamins, sterols and pigments make an even lesser contribution (8). This is graphically demonstrated by Figures 1 and 2. At a constant temperature and radiation dose, production of C_5 to C_8 alkanes was three to five times greater when high fat (35 percent) beef was irradiated than when lean specimens (5 percent) were similarly exposed. The concentration of acetaldehyde also increased with increasing fat content, albeit at a much lower rate. On the other hand, the amounts of benzene, toluene and dimethyl disulfide increased only slightly, if at all, after irradiation of the high fat compared with the lean beef samples. This is consistent with the contention that these latter compounds come from nonfat sources (8).

A major effort has been made to elucidate the mechanism of fat radiolysis. Merritt and Nawar and their respective co-workers have been the leading investigators in this area. Merritt *et al.* (10) were the first to point out that the chief products of fat irradiation are saturated and unsaturated aliphatic hydrocarbons. Subsequent studies confirmed and extended these observations (5, 9). Nawar's group (3, 11) using

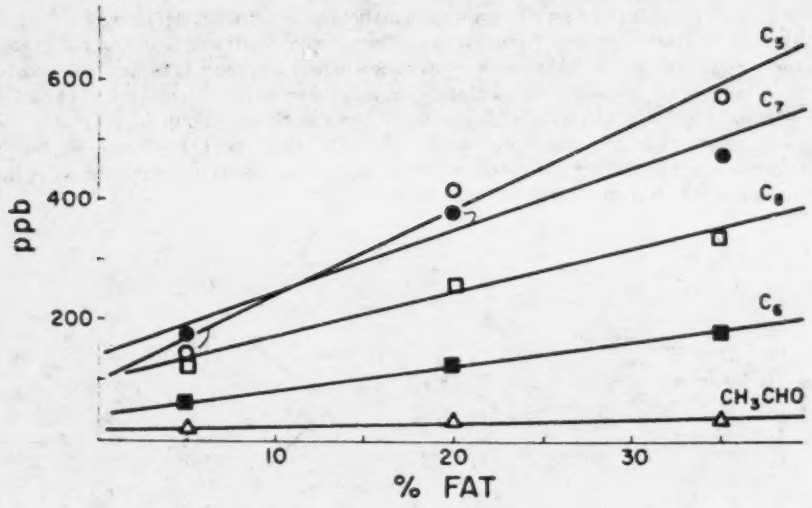


Figure 1. Effect of fat content on component concentrations. Irradiation temperature: -30°C, dose 45 kGy (4.5 megarads). From 7 with permission.

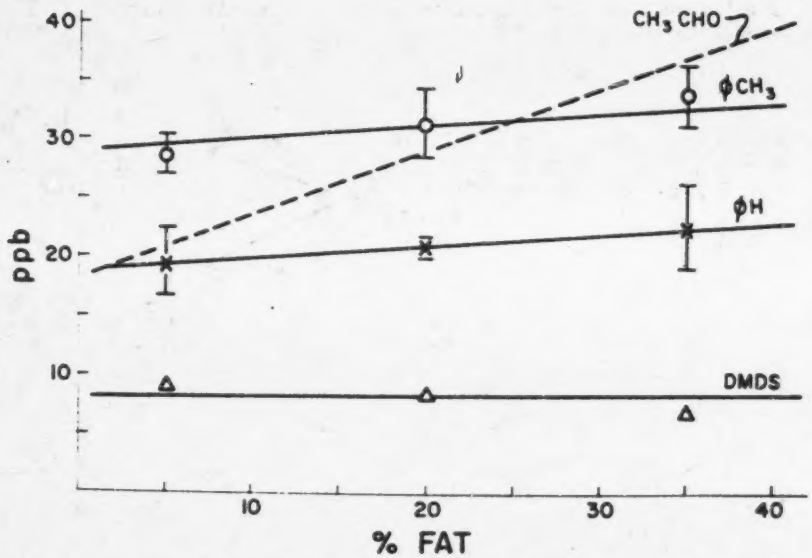
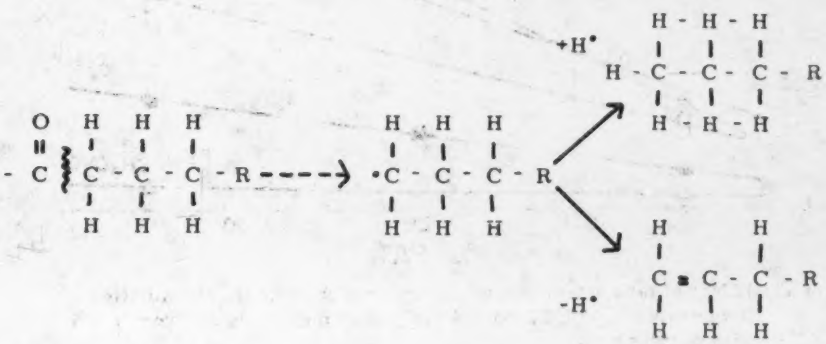
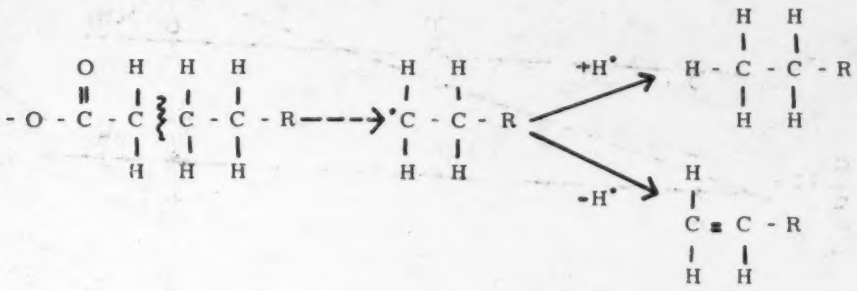


Figure 2. Effect of fat content on component concentrations. Irradiation temperature: 30°C, dose 45 kGy (4.5 megarads). From 7 with permission.

purified model systems, has been especially successful in defining the pathway of hydrocarbon formation. They have confirmed the production of homologous series of alkanes and alkenes when various fats are irradiated and have provided persuasive evidence of the mechanism involved. They have demonstrated that carbon bonds near the carbonyl group of the fatty acid or triglyceride are the most vulnerable to cleavage (3). If the carbon alpha to the carbonyl is ruptured, alkanes and alkenes are produced with one carbon less than the parent fatty acid:

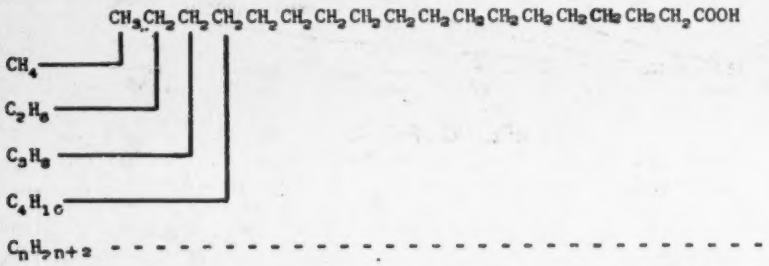


If the beta carbon bond is ruptured, the resulting alkanes and alkenes possess two carbons less than the original acid:



These C_{n-1} and C_{n-2} alkanes and alkenes are the most abundant products of lipid irradiation. If the original fatty acid is unsaturated, the production of an additional double bond by irradiation results in a diunsaturated hydrocarbon, or diene. Thus, oleic acid, the most common unsaturated compound in animal fat (C18:1), yields significant quantities of hexa- and heptadecadiene after irradiation. Similarly, irradiation will convert a diunsaturated fatty acid (linoleic) to a triene and a triply unsaturated member to a tetraene.

Although preferential scission occurs near the carbonyl grouping any of the carbon bonds in the fatty acid chain can be broken by irradiation to produce the entire gamut of hydrocarbons from C_1 to its C_{n-1} homologue. Stearic acid, for example, could yield all hydrocarbons from methane to heptadecane:



The amount and structure of the hydrocarbons produced will depend on the fat content of the meat and on the fatty acid composition of the lipid.

Oxygen compounds, with the exception of carbon dioxide, are usually found in modest amounts in irradiated beef. Carbon dioxide is produced in large amounts from the decarboxylation of the fatty acids. Small amounts of aldehydes and ketones are generated after irradiation of beef, even in the absence of oxygen. They, too, are believed to originate from the fat, presumably from cleavages within the glyceryl moeity adjacent to the ester linkage (9). Ethanol is detected in irradiated beef but not after irradiation of dry triglycerides or fatty acid esters (6).

The small amounts of sulfur and aromatic compounds resulting from radiolysis probably come from direct bond cleavage of amino acid moeities. Merritt et al. (8) could find no evidence for the rupture of peptide bonds. The main products from protein irradiation originated from the cleavage of side chains or end groups. The aromatic amino acids or those with sulfur groups seem the most radiosensitive. Benzene

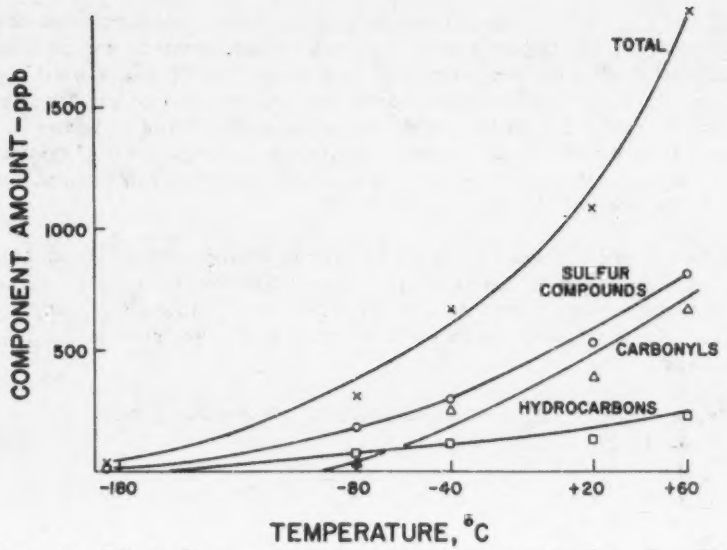


Figure 3. Effect of temperature on component concentration. Irradiation dose 45. kGy (4.5 megarads). From 9 with permission.

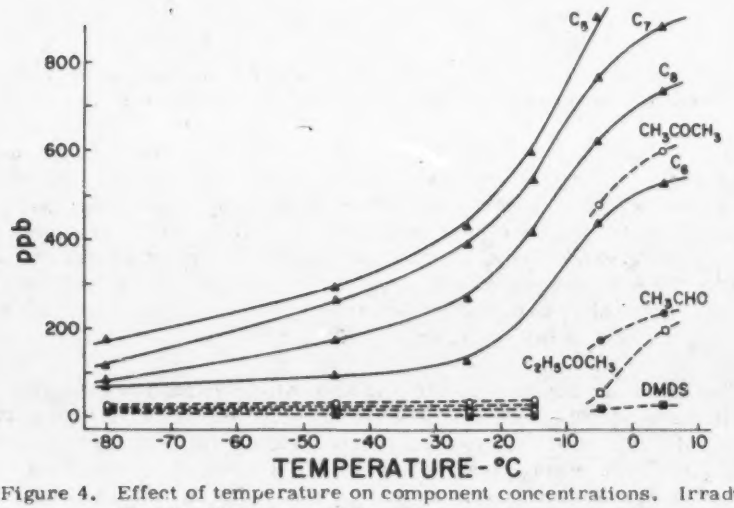


Figure 4. Effect of temperature on component concentrations. Irradiation 45. kGy (4.5 megarads). From 7 with permission.

and toluene are thought to be produced from phenyl alanine while sulfides, disulfides and mercaptans are derived from methionine or cystine (6). The contribution from the steroids is minor and is generally ignored. Cholesterol irradiated at 60 kGy (6 megarads) gives rise to a series of normal alkanes C_1 to C_7 as well as to isoalkanes (C_4 to C_8) (8). These products are most likely derived from the cleavage of the alkyl side chain of cholesterol. A recent publication provides an excellent discussion of the radiolytic products from various food components (4).

B. TEMPERATURE

The quantities of radiolytic products in beef are related directly to the irradiation temperature. Figure 3 shows the amounts of volatile compounds produced in beef related to the temperature at which the meat was irradiated (9). All products increased with increases in temperature between -185° and +60°C. The effect of temperature on the production of representative individual compounds is shown in Figure 4. The characteristic irradiation odor and flavor also became more apparent as the irradiation temperature increased. An expert flavor panel had no difficulty in identifying the beef irradiated at the higher temperatures (9).

Although volatiles are minimal at extremely low temperatures, economic considerations dictate that the irradiation be accomplished at a somewhat higher temperature. The most favorable compromise among quality, cost and irradiation requirements is about -30° ± 10°C (12).

C. DOSE

Merritt and colleagues (10) demonstrated a linear relationship between irradiation dose and the production of radiolytic compounds. In fact, this relationship is an excellent test to determine whether a given compound was of radiolytic or nonradiolytic origin. Figure 5 shows that the concentration of volatiles increases steadily as the irradiation dose increases.*

*The absolute and relative quantities shown in the figures in this section differ significantly from the data in Table 1 because of differences in the fat content and irradiation doses of the respective samples. For example, the data for Figure 5 shows lesser amounts of hydrocarbons in comparison with the sulfur and carbonyl compounds and reflects the low fat content (2 to 3 percent) of this sample. The values in Table 1 are from beef with a fat content of 10 to 12 percent.

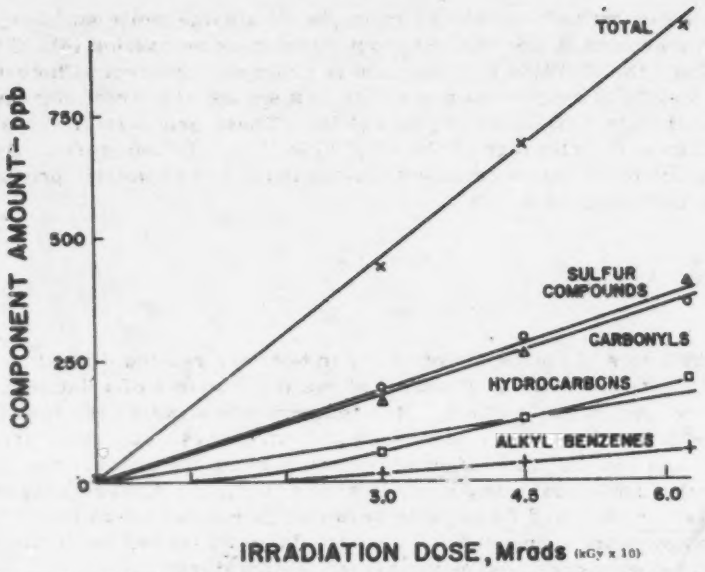


Figure 5. Effect of irradiation dose on component concentration. Irradiation temperature -40°C. From 9 with permission.

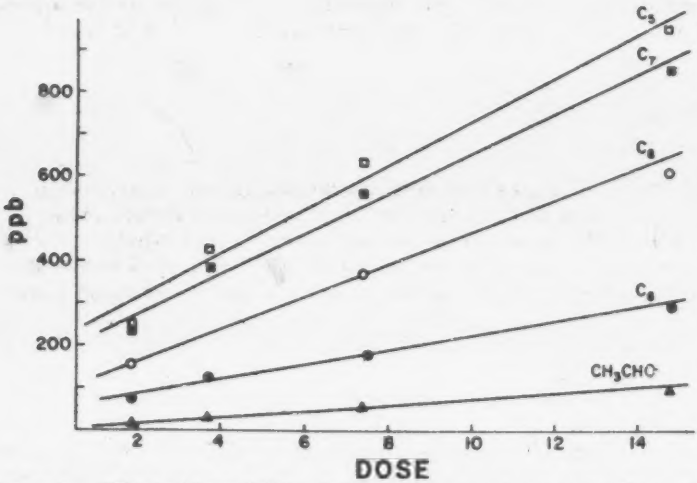


Figure 6. Effect of irradiation dose on component concentration. Irradiation at -30°C. From 7 with permission.
(To convert to kGy, multiply megarads by 10)

Figure 6 shows the concentrations of several hydrocarbons and of acetaldehyde found in beef as a function of radiation dose. A linear relationship between dose and radiolytic product exists over the entire dose range studied, with the concentrations of hydrocarbons rising more rapidly than those of the aldehyde.

At an irradiation temperature of about -40° C the minimum radiation dose for microbiological safety of beef is 41 kGy (4.1 megarads) (1). This represents the radiation dose required to reduce by a factor of 10^{12}, the number of viable spores of the most radiation-resistant strains of Clostridium botulinum. In the present study the dose averaged 56 kGy (5.6 megarads).

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V. EVALUATION OF HEALTH EFFECTS

Designating "safe" levels for the intake of specific substances is a perennial, elusive and perhaps impossible goal. The goal is an ever-moving target, constantly changing as new data become available and analytical techniques become more sensitive. Absolute safety can never be assured. Nevertheless, assessments of safety are often required even when data are not always adequate. In the face of this dilemma, prudence suggests that realistic guidelines be developed to gauge the potential benefit and hazard of products to which the public is exposed. Various expert commissions have attempted to formulate such guidelines for food additives, but no universally acceptable criteria have yet been established.

Perhaps the most widely employed concept is that of margin of safety, based on some fraction of the largest dose of a substance that can be given to animals or man without causing adverse effects. Often 1 percent of the minimum toxic dose, determined experimentally in animals is considered safe for man (2). This is an arbitrary measure, with the obvious dangers of extrapolating from animal to human exposures and of variations in individual sensitivity.

A more arbitrary guideline is the attempt by some bodies to specify an absolute quantity of a substance as "toxicologically inconsequential" or "toxicologically insignificant." Values of 1 to 10 parts per million in foodstuffs have been suggested by various groups. The Committee believes this "guideline" to be potentially dangerous for many substances, such as aflatoxin, plutonium, botulinum toxin, dioxin and others, are serious health hazards at even lower levels.

Other criteria of safety suggested by one or another working group include the long-term consumption of a substance without apparent hazard; its presence in foods; a chemical similarity with compounds of known low toxicity; its rapid metabolism to innocuous products or its occurrence as a natural constituent or metabolite of the human body. A frequently used criterion is that of "added burden." This is interpreted as the potential increment of hazard added to that received from other sources.

The Committee utilized all of these factors and other relevant evidence in its consideration of each compound in irradiated beef. No substance was arbitrarily dismissed because of "insignificant" or "inconsequential" concentrations. The Committee found, as have other groups concerned with similar questions, that the available experimental and clinical data were at times insufficient to permit an unequivocal decision.

In these cases, the Committee's judgment is based on the best available evidence.

The various types of evidence considered by the Committee are discussed in more detail below.

A. POSSIBLE ORIGIN

As stated in the introduction, the irradiation of food has been defined by the statutes of the Food and Drug Administration as an "additive" rather than as a "process" (21 CFR 179.21, formerly 121.3001) (4). Consequently, the regulations governing food additives must be applied to irradiated foods. Although most of the compounds under discussion increased significantly after irradiation, several showed no change from the frozen control levels and cannot be considered as radiolytic products. Other compounds increased more after thermal sterilization than after irradiation. The concentrations of these compounds in frozen control, thermally sterilized and irradiated beef are compared in Table 2.

Table 2. Concentration of selected compounds in irradiated and nonirradiated beef.

Compound	Cooked			Uncooked		
	Frozen control µg/kg	Thermally sterilized µg/kg	Irradiated µg/kg	Frozen control µg/kg	Thermally sterilized µg/kg	Irradiated µg/kg
Acetronitrile	6	21	3	3	57	1
Carbonyl sulfide	0	75	2	0	16	2
Dimethyl sulfide	0	7	3	0	13	4
Hexene	1	22	2	1	31	34
Hydrogen sulfide	0	1	2	0	5	2
Methanol	41	23	16	0	40	20
2-Methyl butane	0	<1	4	0	143	21
2-Methyl heptane	4	27	12	4	47	27
Toluene	3	48	50	6	73	66
Tetra-chloroethylene	10	9	9	12	11	8
Xylene	1	7	4	1	7	1

B. ACCEPTABLE DAILY INTAKE (ADI)

A working party commissioned by the Council of Europe and representing 17 countries reviewed the toxicology of a number of widely used flavoring substances and recommended acceptable levels of daily intake in those cases where it deemed the data to be adequate (1). Five of these compounds are among those detected in the irradiated beef. These compounds and their concentrations in beef are listed in Table 3, together with the Council of Europe's ADIs. For each of these compounds, the ADI is at least several hundred times the amount one would normally ingest from beef.

Table 3. Comparison of acceptable daily intakes and quantities from beef.*

Compound	ADI		Concentration in irradiated beef	Daily beef intake (DBI)	ADI/DBI
	concentration	mg	μg/kg	mg	(ratio)
Dimethyl sulfide	1.5 ppm	2.25	5	.0006	3750
Dodecanal	1.0 mg/kg	70.0	63	.0076	9210
Ethyl mercaptan	1 ppm	1.5	9	.0011	1364
Tetradecanal	3 ppm	4.5	54	.0065	692
Undecanal	5 ppm	7.5	76	.0091	824

*The following average values were assumed in this table: average weight - 70 kg; daily food consumption - 1.5 kg; daily beef consumption - 0.12 kg. According to the American Meat Institute, the per capita annual consumption in the U.S. was 43.3 kg of dressed beef in 1976.

C. DISTRIBUTION IN FOOD AND BEVERAGES

Virtually all the compounds detected in the irradiated beef are present in other foods. Some of the simpler compounds such as methanol, ethanol, butanone, etc. have been identified in almost every food or beverage in which they were sought. In many cases, the amounts in widely consumed foods are considerably greater than in the irradiated beef. Thus, cheese is richer in ketones, eggs in sulfur compounds, citrus fruits in aldehydes and apples in certain hydrocarbons. Although the presence of a compound in a common food does not assure its safety, it does provide a standard against which the amount in beef can be compared. In addition, these data help gauge the "added burden" of substances that might be ingested from irradiated beef. It seems unlikely that the irradiated meat would constitute a significant hazard if its consumption contributed only a very small fraction of the amount of a compound entering the body from other sources. Perhaps the most striking example of the relatively trivial

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addition from beef to the overall intake is that of ethanol. A person consuming one kg of irradiated beef daily throughout a long lifetime would ingest only a small fraction of the ethanol contained in a single glass of wine.

D. AUTHORIZATION BY FOOD AND DRUG ADMINISTRATION

The Food and Drug Administration authorizes the use of certain solvents and additives in the preparation and preservation of various foods (3). In some cases, the compound is authorized by name; in other cases oils or solvents with well-defined boiling or melting point ranges are indicated. Thus, dodecanal is specifically authorized as a synthetic flavoring substance, methanol as an extractant and butane as an oxygen displacer. Implied rather than specific permission is given to certain alkanes found in irradiated beef since they fall within the authorized boiling range of "odorless, light, petroleum hydrocarbons," which is a permitted additive for a number of foods. Similarly, other aliphatic hydrocarbons in irradiated beef are present in mineral oil which is authorized for certain food usages. Table 4 summarizes the various regulations in which the compounds in irradiated beef are either explicitly or implicitly authorized in food. It should be noted that more than one-third of the compounds identified in irradiated beef are found in this list, including all of the straight-chain alkanes except pentane.

E. TOXICITY OF METABOLIC PRODUCTS

Any evaluation of the toxicity of a compound must include consideration of its metabolic transformations in the body. Unfortunately, these pathways are not always known so that the fate of some compounds must be inferred by analogy to related substances whose metabolism has been studied more thoroughly. Available evidence suggests that alkanes and the oxygenated compounds are converted through well-recognized metabolic pathways. The metabolism of alkenes, alkynes and certain other compounds is not as well known. The fate of the individual compounds will be considered in detail in the following sections of this report.

Table 4. Pertinent regulations of the Food and Drug Administration.

Authorized substance	Use	Residue limits	Compounds included	Regulations: Former reference	Regulations: Revised reference
				21 CFR	
Acetone	Extractant: spices	30 ppm	Acetone	121.1042	173.210
Butane	Additive "Generally recognized as safe"	None stated	Butane	121.101	182.1165
	Antioxidant	None stated		121.1060	-
Ethanol	Antimicrobial agent	2% by weight	Ethanol	121.104	182.1293
Hexane	Extractant:		Hexane	121.1045	173.270
	Spices	25 ppm			
	Hops	2.2%		121.1082	172.560
	Hop extract	25 ppm			
Isoparaffinic petroleum hydrocarbons	Cleaning vegetables	None stated	2-Methyl heptane*	121.1154	172.882
	Insecticide component	None stated			
	Fruit, vegetable coating	None stated			
	Vinegar, wine manufacturing	None stated			
	Defoaming agent	150 ppm (yeast)		121.1099	173.340
Light petroleum hydrocarbons	Fruit, vegetable coating	None stated	Nonane*	121.1182	172.884
	Vegetable cleaning	None stated	Decane*		
	Food processing	None stated	Undecane*		
	Vinegar, wine manufacturing	None stated	Dodecane*		
	Defoaming agent	150 ppm (yeast)	Tridecane*	121.1099	173.340
			Tetradecane*		
			Pentadecane*		
			Hexadecane*		
			Heptadecane*		
Methanol	Extractant:		Methanol	121.1044	173.250
	Spices	50 ppm			
	Hops	2.2%		121.1082	172.560
	Hop extract	100 ppm			
Mineral oil	Animal feed	0.06% of ration	Tetradecane*	121.246	
			Pentadecane*		
			Hexadecane*		
			Heptadecane*		
	Release agent	0.02-0.6%		121.1146	172.878
	Binder	0.02-0.6%			
	Lubricant	0.02-0.6%			
	Defoaming agent	150 ppm (yeast)		121.1099	173.340
Petrolatum	Animal feed	0.08 % of ration	Heptadecane*	121.261	
	Coating	0.02-0.2%		121.1166	172.880
	Lubricant	0.02-0.2%		121.	
	Defoaming agent	150 ppm (yeast)		121.1099	173.340
Petroleum naphtha	Extractant	None stated	Heptane*	121.1203	172.250
			Octane*		
Petroleum wax	Coating	None stated	Heptadecane*	121.1156	172.886
	Chewing gum base	None stated		121.1156	172.888
Propane	Additive - "Generally recognized as safe"	None stated	Propane	121.101	182.1655
	Antioxidant	None stated		121.1060	
Synthetic flavoring substances	Flavoring	None stated	2-Butanone	121.1164	172.515
			Dodecanal		
			Dimethyl sulfide		
			Tetradecanal		

*Within range of specified melting or boiling points.

F. DATA FROM CONVENTIONAL TOXICITY STUDIES

Although considerable toxicity data are available for many of the compounds under consideration, they are of limited utility in the present study since routine tests generally utilize single exposures to large doses. This method enables investigators to establish the LD_{50}, LD_{100}, minimum lethal dose or least toxic dose of a compound. It provides a crude index which allows one to distinguish among highly, moderately, and mildly toxic compounds. It has little relevance, however, to the problem of irradiated beef where the concern is with possible toxicity induced by repeated ingestion of small doses of a compound. Long-term studies at modest dose levels would be more informative, but are rarely reported.

Another difficulty in utilizing the available toxicity data to evaluate the compounds in irradiated beef lies in the different routes of administration. A number of the volatile compounds in irradiated beef are widely used as industrial solvents and have been carefully studied for their safety in the factory or shop. However, the primary objective of these toxicological studies has been to establish permissible levels in the workroom atmosphere, and it is difficult to utilize such data in estimating the toxicity of a compound when ingested in food. In the first place, data on the retention of inhaled compounds are scarce and not always reliable. Then, too, a compound absorbed through the lungs may undergo a fate different from that it would experience after enteral absorption. This would be particularly true for compounds that are metabolized in the lung or the liver, so that one cannot interchange with any assurance toxicity data between the two routes.

G. CARCINOGENICITY, MUTAGENICITY AND TERATOGENICITY

In recent years, some compounds long believed to be innocuous, have been implicated in tumor production, genetic alteration or birth abnormalities. The traditional toxicological indices must therefore be increased to include these parameters. Regulations concerning the possible carcinogenicity of food additives are particularly stringent. Consequently, tetrachloroethylene (perchloroethylene), benzene and certain alkenes have been scrutinized with especial care despite their low concentrations in irradiated beef. Tetrachloroethylene in very high doses has recently been shown to cause liver tumors in mice (3). Benzene is a suspected leukemogen in man, while the alkenes in their metabolism produce epoxides, some of which may be carcinogenic. These will be discussed in the appropriate sections.

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VI. ANALYSIS OF INDIVIDUAL CHEMICAL CLASSES

A. HYDROCARBONS

1. Alkanes

Occurrence

The concentrations of alkanes in cooked and uncooked samples of frozen controls and of heat- and radiation-sterilized beef are listed in Table 5. The table also includes data on the occurrence of these compounds in air, water and food. These data strongly suggest that the straight-chain alkanes are products of radiolysis for the irradiated beef contains each in a higher concentration than in the thermally sterilized samples or in the frozen controls. On the other hand, the branched compounds, except for 2-methyl propane, are found in equal or greater amounts in the thermally sterilized meat.

It is also apparent from Table 5 that many of these alkanes are common in our environment. They are found in air and water and in many foods, including untreated or cooked meats, vegetables, fruits, nuts, and dairy products. Quantitative data are not generally available, but single studies on apples (24) and eggs (20, 21) reported concentrations of the higher alkanes comparable with or greater than those found in irradiated beef. There is also evidence that some of these compounds are produced during cooking and that their content in beef is higher after microwave than after conventional cooking (22).

The lower members of the alkane series are gaseous or highly volatile at normal temperatures. They are used widely in industry as fuels, lubricants, solvents and feed-stocks for numerous chemical processes. It is not surprising, therefore, that many of these members have been detected at significant levels in metropolitan atmospheres and water supplies.

Absorption and Metabolism

All of the volatile alkanes are absorbed through the pulmonary system and their retention closely parallels the fat content of the body and tissues. Rats exposed to high concentrations of hexane vapor (170 g/m^3) for 2 to 10 hours, revealed an average tissue concentration of approximately 4 mg per g of lipid (2). Equilibrium concentrations

Table 5. Presence of alkanes in various media.[a]

Compound	Irradiated beef μg/kg		Thermally sterilized beef μg/kg		Frozen beef control μg/kg		Atmosphere μg/m³	Water μg/l	Food μg/kg
	Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked			
Ethane	0	176	0	0	0	0	Los Angeles - 120 Hawaii - 10		No quantitative data, detected in apples, chicken, strawberries, vinegar
Propane	63	169	0	0	0	0	Los Angeles - 90 Hawaii - 9		No quantitative data, detected in chicken
Butane	126	215	0	0	0	0	Los Angeles - 150		Detected in canned beef
Pentane	175	204	4	8	2	1	Los Angeles - 63 Simulated spacecraft - 53	U.S. (max) 1.0	Beef, canned - 160; rum, Jamaican - 50; also found in fruits, dairy products, vegetables
Hexane	228	213	67	125	7	6	Los Angeles - 40 Simulated spacecraft - 31		Beef, canned - 29; rum, Jamaican - 50; also found in approximately 15 other foods
Heptane	290	428	62	102	8	10	Zurich - 140 Simulated spacecraft - 120		Rum, Jamaican - 50; also found in approximately 20 foods
Octane	293	358	0	47	0	0	Zurich - 16 Simulated spacecraft - 58	Detected in U.S. drinking water	Eggs - 2800; beef, canned - 7.5; also found in approximately 20 foods
Nonane	136	266	0	0	0	0	Zurich - 9 Los Angeles - 26	U.S. drinking waters -0.03-10.0	Eggs - 1900; found in approximately 15 foods
Decane	180	362	?	0	?	0	Zurich - 10	U.S. (max) - 2.4	Apples - 420; also found in approximately 15 foods
Undecane	210	176	?	0	?	0	Zurich - 7	U.S. (max) - 0.02 Effluents from oil refineries, paper mills, etc.	Eggs - 1100; apples - 330; also found in approximately 20 foods
Dodecane	306	207	?	0	?	0	Zurich - 9	U.S. (max) - 0.4 Effluents from oil refineries, paper mills, etc.	Eggs - 4900; apples - 240; also found in approximately 20 foods

Tridecane	[b]	321	[b]	0	[b]	0		U.S. (max) - 0.3 Effluents from paper mills, oil refineries and textile mills	Eggs - 700; apples - 240; also found in fruits, nuts, meats, dairy products
Tetradecane	[b]	313	[b]	0	[b]	0		U.S. (max) - < 1.0 Effluents from textile mills	Eggs - 3600; apples - 380
Pentadecane	[b]	696	[b]	0	[b]	0		U.S. (max) - 0.5 Effluents from oil refineries, paper mills	Eggs - 22, 200; apples - 380; also found in approximately 20 other foods
Hexadecane	[b]	221	[b]	0	[b]	0		Detected in U.S. drinking water Effluents from oil refineries, paper mills, nylon plants	Eggs - 1100; apples - 280; also found in meat, dairy products, vegetables
Heptadecane	[b]	394	[b]	0	[b]	0			Eggs - 1200; apples - 240; also found in meat, vegetables, dairy products, fruits
2-Methyl propane	28	46	0	0	0	0	Los Angeles - 28		Found in whiskey
2-Methyl butane	5	21	0	143	0	0	Los Angeles - 105		Found in apples
2-Methyl pentane	11	34	1	28	1	0			Rum, Jamaican - 10; also found in apples and cheese
2-Methyl heptane	12	27	27	47	4	4	Zurich - 16		Found in chicken

[a] Data on the distribution of the compounds listed in this and in subsequent tables have been compiled from numerous sources making it impractical to cite each reference. The following references have been especially valuable: 4, 8, 19, 25, and 32.
[b] Not determined.

in most tissues occurred in 4 to 5 hours. When exposure was terminated, the volatile hydrocarbons were rapidly eliminated unchanged in the expired air. This fact was demonstrated with human volunteers who breathed approximately 100 ppm of hexane for 4 hours. When returned to ambient air, the subjects rapidly eliminated the hexane and within 4 hours, its concentration in the expired air was less than 0.5 ppm (26).

Little is known about the absorption of alkanes from the gastrointestinal tract, but the degree of absorption seems to depend on the molecular dimensions of the hydrocarbon. Mineral oil, consisting largely of paraffins with 15 to 30 or more carbon atoms, is poorly absorbed (17). On ingestion, only 2 percent is absorbed and this presumably represents the shorter members of the series. Slight, but significant, absorption of hexadecane (3, 7) and heptadecane (31) occurred in rats fed small amounts daily. Longer chain paraffins were more poorly absorbed.

Because of their relative physiological and pharmacological inactivity, the metabolism of alkanes has not been studied as thoroughly as more reactive substances. Consequently, the precise metabolic disposition of many of these compounds is not known and can only be surmised from investigations on some of their homologues.

In common with a number of lipid-soluble organic compounds, the metabolism of alkanes and isoalkanes is catalyzed by microsomal mixed-function oxidases (MFO) (12). This ubiquitous, highly inducible enzyme system (5, 11) found in most tissues of all higher organisms, is generally associated with the metabolism of steroids and a wide variety of xenobiotics, including drugs and pesticides. Both low and high molecular weight alkanes such as butane (10), pentane (10), heptane (6), decane (15), and hexadecane (19) are oxidized to the corresponding alcohol by this system. Although all of the alkanes found in irradiated beef have not been studied, it seems reasonable to conclude that they are metabolized in the same way as their higher or lower homologues.

Among the simpler alkanes, the preferred site of attack is the tertiary CH bond, with the secondary bond the next most susceptible and the primary methyl group the most resistant to the hydroxylation reaction (10). Thus, n-butane on oxidation yields 2-butanol with only traces of the primary alcohol. Similarly, 2-pentanol is the major product of n-pentane hydroxylation. Significant amounts of 3-pentanol but only barely detectable amounts of the primary alcohol (1-pentanol) are also produced.

However, the higher alkanes are apparently oxidized preferentially at the terminal carbon atom. Heptane is oxidized by MFO to 1-heptanol (6)

and decane to 1-decanol, with equal facility by lung, kidney or liver microsomes (15).

The ultimate fate of the alcohols produced from the alkane hydroxylation is not known with certainty. Some are probably conjugated and excreted in the urine as glucuronides (18) while some may be metabolized further to the corresponding fatty acid (19, 23), a fate clearly demonstrated for hexadecane and octadecane. Hexadecane was converted by the MFO and other enzymes to cetyl alcohol and palmitic acid (19), the latter presumably by further oxidation of the alcohol. In contrast with their activity in decane oxidation, lung microsomes showed relatively low activity compared with liver microsomes in the oxidation of hexadecane, while the kidney microsomes were completely inactive. Alcohol dehydrogenase catalyzes the oxidation of lower aliphatic alcohols (30) to the corresponding aldehydes, which are then further oxidized to their acids.

Toxicity

The simplest alkane homologues -- methane, ethane and propane -- are generally considered to be innocuous when inhaled at concentrations below 1 percent by volume. Several thousand parts per million of these gases are necessary to produce any detectable physiological effect and even at these levels, the effect is a mild hypoxia resulting from the corresponding reduction of oxygen in the inspired air. No threshold limit values (TLV) have been established for their presence in workroom atmospheres.

TLVs for the intermediate alkane members range from 100 to 600 ppm (1) as shown in the following table:

Table 6. Threshold limit values for alkanes (1).

Compound	ppm	mg/m^3
Butane	600	1400
Pentane	600	1800
Hexane	100	360
Heptane	400	1600
Octane	300	1450
Nonane	200	1050

Propane and butane are used in processing and packaging of foods to remove and displace oxygen and have been approved as GRAS ("generally recognized as safe") by the Food and Drug Administration for this purpose (27). Petroleum hydrocarbon fractions are used as solvents to extract oils from various food preparations. These fractions are mixtures of hydrocarbons boiling within a given temperature range and may include hexane, methyl pentane, heptane, dimethyl butane, and other compounds. Their use, in accordance with good manufacturing practices, has been approved by the Joint FAO/WHO Expert Committee on Food Additives (17). Similarly, FDA regulations permit the use of hexane (21 CFR 173.270; 172.560, formerly 21 CFR 121.1045; 121.1082) 2-methyl heptane (21 CFR 172.882, formerly 21 CFR 121.1154) and heptane (21 CFR 172.250, formerly 21 CFR 121.1203) as solvents for foodstuffs under controlled conditions (27). Also mineral oil which contains high molecular weight hydrocarbons is employed for a variety of food and medicinal purposes (21 CFR 172.878, formerly 21 CFR 121.1146) (27, 17).

Virtually no toxicological data are available for the individual higher molecular weight alkanes. Most of the available reports concern various industrial products consisting of complex hydrocarbon mixtures including some of the C_{10} to C_{17} alkanes. One of the few studies of these higher paraffin members given systemically is that of Jeppsson (16) who injected mice intravenously with emulsions containing various alkanes. The LD_{100} for pentadecane, hexadecane and heptadecane was approximately 10 g per kg for each of these alkanes. Hine and Zuidema (13) administered the following mixtures of paraffins and naphthenes intragastrically to rats at concentrations of 25 ml per kg without causing death in any of the animals: C_9 and C_{10}; C_{11} and C_{12} and C_{13} through C_{18}.

None of these alkanes has proved carcinogenic but some have enhanced ("promoted") the development of papillomas in mouse skin pretreated or "initiated" with subcarcinogenic doses of polycyclic aromatic hydrocarbons. Sice (29) "initiated" the skin of female Swiss mice with 7,12 dimethylbenz (a)anthracene and subsequently applied a number of alkanes and alkanols. The skin tumor incidence/number of mice were as follows: hexane (0/30), octane (0/40), decane (2/30), dodecane (6/30), tetradecane (5/30), hexadecane (1/50) and octadecane (1/30). The latent period before tumor appearance promoted by dodecane and tetradecane was 20 to 60 weeks, compared with more than 50 weeks with decane and octadecane.

Similar conclusions were reached in an experiment with dodecane (28) and in a more recent series of experiments by Horton et al. (14) in which male C3H mice were treated repeatedly with 0.14 percent benzo(a) pyrene dissolved in certain alkanes or in decalin (decahydronaphthalene). Benzo(a) pyrene in decalin alone caused 33 percent malignant tumors while benzo(a) pyrene with dodecane, hexadecane, octadecane and eicosane produced

malignant skin tumors in all of the animals. These experiments suggest that chronic exposure to high concentrations of some alkanes can enhance the production of tumors "initiated" by polycyclic aromatic hydrocarbons, but gave no indication that the alkanes alone were carcinogenic.

Discussion

Each of the alkanes found in irradiated beef has occurred in other foods, sometimes more abundantly than in the irradiated beef. Their origin in many of these foods is unknown. A number of the alkanes are employed as solvents or in preparations approved for various purposes by the Food and Drug Administration and by official international bodies. The lower homologues are common industrial substances whose threshold limits in workroom atmospheres are several orders of magnitude greater than their concentrations in beef. A similar margin of safety exists for each of the compounds whose least toxic effect has been determined. Some of the metabolic products of these substances, where known, are either compounds normally found in the body or substances metabolized by known physiological processes to compounds believed to be nontoxic.

The Committee carefully reviewed the data demonstrating that several of the higher alkanes and alkanols may act as co-carcinogens or tumor-promoting agents in mice pretreated with polycyclic aromatic hydrocarbons. The possibility seems slight that alkanes in the quantities found in irradiated beef are co-carcinogenic. Not only were the alkanes applied in the presence of a large concentration of a known carcinogen, but their doses were huge in comparison with the amounts found in beef.

The available data on the alkanes suggest that the consumption of irradiated beef would not pose a significant increment of hazard to the amounts an individual would be unavoidably exposed.

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2. Alkenes and Alkynes

Although the most apparent effect of lipid irradiation is the production of n-alkanes with one or two less carbon atoms than the original fatty acids, significant amounts of unsaturated hydrocarbons are also produced. Simple alkenes are produced from saturated fatty acids while dienes are generated from the monounsaturated acids.

Occurrence

The alkenes and alkynes and their concentrations found in the variously treated beef samples are listed in Table 7 as are their concentrations in air, and in other foods.

As might be expected, almost the entire series of straight-chain alkenes, from C_2 to C_{17}, has been identified in the irradiated beef. An exception is propene which was not detected. Heptadecene and hexadecadiene are the most abundant of the unsaturated hydrocarbons with 618 and 706 ug per kg beef, respectively. The former is presumably generated from stearic acid and the latter from oleic acid, among the most common fatty acid constituents in beef. Traces of decyne and undecyne have also been detected. The precursors of these highly unsaturated compounds are unknown.

Each of the mono-alkenes has been detected in certain foods, but there have been few attempts to provide quantitative data. A single report suggests that eggs are a particularly rich source of these compounds (13, 14) and several of the higher homologues --- nonene, undecene, pentadecene, hexadecene and heptadecene --- appear to be present in concentrations considerably greater than any alkene in the irradiated beef. All alkenes from hexene through heptadecene have been found in cooked beef and most members of this series have also been detected in other meats and dairy products. The amounts are generally greater in beef when cooked by microwave than by conventional means (15), presumably because of the rapid rate of heating. Every member of the series C_2 to C_{17} has been found in coffee or in some fruit or vegetable (26). Some dienes and alkynes also appear in food, but no reference could be located to indicate the presence of pentadecadiene, hexadecadiene and undecyne in any food.

Ethene is exceeded only by methane as the major hydrocarbon emitted into the atomsphere from automotive exhausts (19). Lesser but significant amounts of other low molecular alkenes --- propane, methyl propene, butene and hexene --- are also present in exhaust fumes (18).

Table 7. Presence of unsaturated hydrocarbons in various media.[a]

Compound	Irradiated beef μg/kg Cooked	Irradiated beef μg/kg Uncooked	Thermally sterilized beef μg/kg Cooked	Thermally sterilized beef μg/kg Uncooked	Frozen beef control μg/kg Cooked	Frozen beef control μg/kg Uncooked	Atmosphere μg/m³	Food μg/kg
Alkenes								
Ethene	0	28	0	0	0	0	Washington - 800 Los Angeles - (ave) 120, (max) 820 Pasadena freeway - 820; S. Pasadena - 410; incinerator - 1400-5600	Found in apples, coffee, grapes, pears, peaches, mushrooms, tomatoes, strawberries
Butene	13	33	0	0	0	0	Los Angeles - 14	Found in coffee
Pentene	2	37	3	4	3	0		Found in coffee
Hexene	2	35	22	31	1	1		Found in coffee, currant, cooked beef
Heptene	46	114	12	31	2	1		Eggs - 900; also found in apples, cooked beef, milk
Octene	21	96	0	0	0	0		Eggs - 1300; also found in apples, cooked beef, cheese, chicken, coffee, milk, onions
Nonene	41	80	0	0	0	0		Eggs - 1800; also found in apples, cooked beef, cheese, chicken, coffee, milk, onions
Decene	114	126	[b]	0	[b]	0		Eggs - 300; also found in apples, cooked beef, cheese, coffee, milk, onions
Undecene	88	78	[b]	0	[b]	0		Eggs - 2800; also found in cooked beef, cheese, milk, onions
Dodecene	167	158	[b]	0	[b]	0		Found in cheese, eggs, milk, onions, cooked beef
Tridecene	[b]	178	[b]	0	[b]	0		Found in eggs, milk, onions, cooked beef
Tetradecene	[b]	488	[b]	0	[b]	0		Found in eggs, milk, onions, cooked beef
Pentadecene	[b]	121	[b]	0	[b]	0		Eggs - 2800; also found in cooked beef, onions, pork
Hexadecene	[b]	156	[b]	0	[b]	0		Eggs - 3900; also found in onions, pork, cooked beef
Heptadecene	[b]	618	[b]	0	[b]	0		Eggs - 137, 900; also found in cooked beef, milk, onions
2-Methyl propene	2	38	9	4	0	0		Found in hops
Alkynes								
Decyne	24	23	[b]	0	[b]	0		Found in apples, potato chips
Undecyne	10	4	[b]	0	[b]	0		
Dienes								
Tetradecadiene	[b]	98	[b]	0	[b]	0		Found in approximately 15 foods; meat, fish, fruit, dairy products, beverages
Pentadecadiene	[b]	73	[b]	0	[b]	0		
Hexadecadiene	[b]	706	[b]	0	[b]	0		
Heptadecadiene	[b]	16	[b]	0	[b]	0		Eggs - 2000

[a] See table 5, footnote a.
[b] Not determined.

In freeways and in metropolitan areas, the concentration of ethene approximates 400 to 800 μg per cubic meter of air (1, 20) while other alkenes range from 5 to 10 μg per m^3 (21). Hydrocarbons with more than 12 carbon atoms are generally not present in the atmosphere in any significant amounts (16). Butene has been identified in drinking water supplies in the United States (6) but its concentration has not been reported.

The alkenes are employed in large quantities in the manufacture of various industrial products. The simpler members provide the raw material for plastics, those with 8 to 12 carbon atoms are common sources for plasticizers, and the longer members (C_{14} to C_{18}) are used in manufacturing alkyl sulfate detergents.

Metabolism

This class of compounds is oxidized in the body to epoxides by the microsomal mixed function oxidases (MFO). Although the epoxides exhibit a very short half-life and are extremely difficult to isolate, they have been demonstrated to be obligatory intermediates of alkene metabolism (12, 24, 25). They may be unstable and rearrange to unknown products or may be converted to their corresponding diols by epoxide hydratase (9). The diols may then be excreted unchanged, undergo further oxidation, or be conjugated with glucuronic acid (4, 5). Epoxides may react with glutathione with or without enzymatic mediation.

Boyland and Williams (3) reported the direct conjugation of aromatic epoxides by glutathione S-epoxide transferase found in rat liver, but this reaction has not been studied with the aliphatic epoxides. Both enzymatic and nonenzymatic conjugation would depend upon the stability of the aliphatic epoxide intermediate and upon the relative affinities of the glutathione transferase and epoxide hydratase for this epoxide.

The metabolic pathway of the dienes remains virtually unexplored. However a single study with butadiene suggests that this compound, too, is metabolized through the intermediate formation of epoxides. When butadiene was incubated with rat liver fractions, 3-butene 1, 2-diol and erythritol (1, 2, 3, 4-tetrahydroxybutane) were produced (8). These are the compounds one would expect if the oxidation of each double bond proceeded in the same way as those of the monounsaturated alkenes just discussed.

One can only speculate on the fate in the body of the two alkynes, decyne and undecyne, produced by beef irradiation. Phenylacetylene ($C_6H_5C{\equiv}CH$), one of the few related compounds that has been studied, was found to be relatively stable and only slowly metabolized to phenaceturic

acid. Williams (27) postulated an initial hydration of the triple bond to form the enol form of phenylacetaldehyde which was then oxidized to phenylacetic acid, the precursor of phenaceturic acid. He believed a similar pathway is taken by the fluoroalkynes to yield fluoroacetic acid. By analogy, the end products of decyne and undecyne metabolism would be decanoic and undecanoic acids respectively.

Toxicity

Toxicologists have largely ignored the volatile olefins, because they appear to act primarily as asphyxiants in high concentrations and exhibit no discernible harmful effects at low or moderate concentrations. All acute studies on the lower alkenes (C_1 to C_8) indicate that concentrations several orders of magnitude greater than those found in beef are necessary before any significant hazard is produced (2, 7, 11, 17). The Committee believed such studies to be irrelevant to its consideration of the much smaller quantities involved. Toxicity data for the higher alkenes are unavailable.

The demonstration that alkenes are converted metabolically to epoxides raises the possibility of carcinogen formation in vivo. Epoxidation of ethylenic bonds in vinyl chloride, polycyclic aromatic hydrocarbons and aflatoxin B, is thought by many to represent conversion of the pro-carcinogen to its reactive form. The question arises, therefore, whether alkene epoxides represent a carcinogenic hazard. Relevant data are currently confined to skin-painting experiments and have been summarized by Lawley (10). In a series of experiments with Swiss mice, Van Duuren et al. (23) found 1, 2-epoxybutane and 1, 2-epoxydodecane to be inactive but they considered 1, 2-epoxyhexadecane to be tumorigenic since it induced two papillomas and one squamous cell carcinoma in 41 mice surviving an average of 427 days. The Committee questioned the authors' conclusion that these data demonstrated the carcinogenicity of this compound. The possible presence of impurities in the large amounts of test substance used and the very few tumors induced in this experiment raise considerable doubt that 1, 2-epoxyhexadecane is truly a carcinogen.

Van Duuren (22) has pointed out that diepoxides are more apt to be carcinogenic than the monoepoxides. He speculates that this may result from the cross linking of DNA with a consequent alteration of its replication. The ability to effect such cross linkages would depend upon the interatomic distances between the epoxides. No information is available on the diepoxides that could theoretically be produced from the dienes detected in the irradiated beef.

Discussion

As is evident from this brief treatment of the alkenes and alkynes in irradiated beef, significant gaps exist in our knowledge of the metabolism and toxicity of many of these substances. The growing conviction that epoxides may be important in the carcinogenicity of certain chemicals emphasizes the importance of additional, systematic investigations on the metabolism and toxicology of the aliphatic unsaturated compounds.

The total alkenes and alkynes amount to 2.4 mg per kg of irradiated beef for an average daily consumption of approximately 0.3 mg. Each of the compounds under consideration has been identified in other foods, with the exception of penta- and hexadecadiene and undecyne. All of the alkenes from hexene through heptadecene (C_6 C_{17}) have been reported in conventionally cooked beef. As mentioned above, the only analogue of these compounds alleged to produce tumors is 1,2-epoxyhexadecane, a presumed epoxide of hexadecene. Hexadecene has been found in eggs, cooked beef, pork, onions and chicken broth as well as in irradiated beef.

Despite the widespread industrial use of many of these compounds in considerable quantities, no reports of acute or chronic toxicity could be found.

There is insufficient information to permit an unequivocal decision on the long-term effects of small quantities of alkenes. However, based on the available data, the Committee concludes that these compounds, consumed at levels found in irradiated beef, are not likely to represent a significant increment of hazard to that encountered by exposure from unavoidable sources.

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Table 8. Aromatic compounds in various media.*

Compound	Irradiated beef ug/kg		Thermally sterilized beef ug/kg		Frozen beef control ug/kg		Atmosphere ug/m³	Water ug/l	Food ug/kg
	Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked			
Benzene	15	19	2	0	3	0	Los Angeles - (ave) 48 (max) 182 Toronto - (ave) 42 (max) 314 Zurich - 173 Gas stations (ave) 4000 (Max) 11,000 Near reclamation plant - 7360 Bulk loading facilities - 320 - 68,000 Simulated spacecraft - 61	Highest reported in U.S. - 10.0 Canadian lake - 320 Miami - 0.1 Ottumwa - 0.1 Philadelphia - 0.2 Cincinnati - 0.3 Well water - Florida fire station - 300.	Beef, canned (headspace) - 2.0 ppb Rum, Jamaican - 120; Eggs - 2100; Haddock (stored Haddock (stored 14 days) - 200; also detected in approximately 20 other foods - no quantitative data available
Toluene	50	65	48	73	3	6	Delft -(ave) 11 (max) 76 Los Angeles - (ave) 120 (max) 720 Netherlands - tunnel (ave) 150 (max) 240 Toronto - (ave) 140 (max) 460 Nuclear submarine 738	Highest reported in U.S.-11.0 Canadian watershed 375.0 Philadelphia - 0.7 Cincinnati - 0.1 Connecticut - 81-140 Effluents from textile mills	Beef, canned - 5.9; eggs 39,300; Haddock (stored 14 days)- 500; also detected but not analysed in approximately 30 foods
Xylene	4	1	7	7	1	1	Zurich - (ave) 31 (max) 91 Los Angeles (ave) 66 (max) 265 Simulated spacecraft - 122	Highest reported in U.S.- 5.0 Effluents from oil refineries	No quantitative values; detected in approximately 20 foods

*See Table 5, footnote a.

3. Aromatic Hydrocarbons

Three aromatic hydrocarbons have been detected in irradiated beef: benzene, toluene and xylene (Table 8). Irradiation had little, if any effect upon the concentration of xylene, which is apparently not a radiolytic product. On the other hand, the amounts of benzene and toluene varied directly with the irradiation dose (Figure 7), presumably from the action of ionizing radiation upon the amino acid, phenyl alanine (21). Heating alone produced comparable amounts of toluene but not of benzene. Similarly, small amounts of benzene have also been produced after the irradiation of codfish (40).

All three of these compounds have extensive industrial uses and hundreds of millions of gallons are produced annually in the U. S. Of special significance is the presence of benzene in gasoline with the consequent ubiquitous contamination from automotive emissions. It has been estimated that over one billion pounds of benzene per year are emitted into the atmosphere. Significant quantities of benzene, as well as of toluene and xylene, have been detected in the air and water of virtually every metropolitan area in which they were sought.

All three of these compounds have been reported in numerous foods, including meat, vegetables, nuts, dairy products, and beverages (12). "Large" amounts of benzene have been reported in boiled beef (6) and in canned beef stew (6). Thus, conventional cooking, itself, will cause an increase of benzene, probably from amino acid precursors. Benzene and toluene (but not xylene) have also been detected in fruits, fish and eggs. In common with most of the compounds under consideration, quantitative data are scarce. Eggs appear especially rich in aromatics if a single report is typical, for their content of benzene and toluene is estimated to be more than a hundred times that in the irradiated beef (18, 19). Large amounts of both these compounds were also found in haddock kept under refrigeration for 14 days; as much as 200 μg per kg of benzene and 500 μg per kg of toluene (20).

Absorption and Metabolism

These compounds are usually rapidly absorbed through the lungs although significant absorption through the skin and gut is also possible. Human subjects exposed for 4 hours to 52 to 62 ppm benzene or to 98 to 130 ppm toluene had an apparent retention of 30 to 40 percent of the hydrocarbon inhaled during that period (28). No comparable data are available for xylene. After exposure ceased, elimination of the unchanged solvents through the lungs continued for many hours (29). When labeled benzene was given orally to rabbits, 43 percent was recovered unchanged in the expired air, 34.5 percent in the urine as phenolic conjugates and 0.5 percent in feces within 2 to 3 days (32). Similarly, benzene injected subcutaneously in mice was

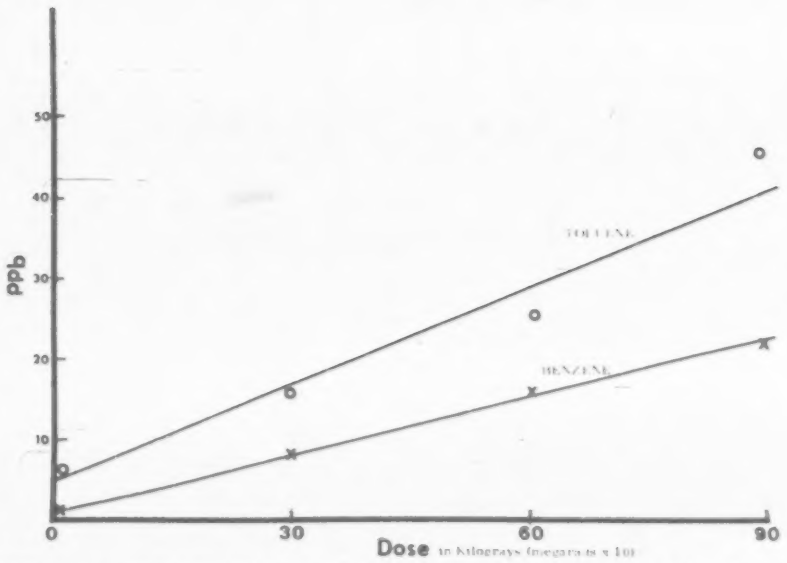


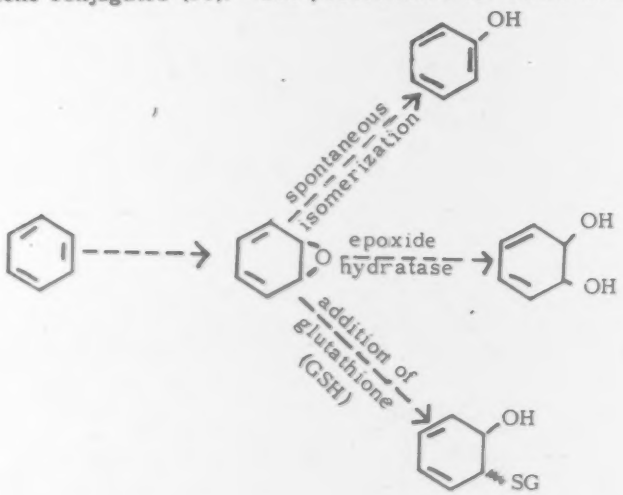
Figure 7. Benzene and toluene production as a function of irradiation dose. From C. Merritt, Jr., unpublished.

recovered in large part (70 percent) in the expired air (39). The major urinary products were phenolic glucuronides and ethereal sulfates, with small amounts of free phenol and catechol.

Toluene, too, may be excreted unchanged through the lungs or, as metabolic conjugates, through the kidney. In contrast with benzene, urinary excretion is the preferred route, accounting for 80 percent of administered toluene (30). Most of the toluene is converted to benzoic acid, which is then conjugated with glycine and excreted as hippuric acid. Small amounts of benzyl alcohol and ortho and para cresol may also be detected.

The pathways in the body of the xylene isomers are similar to that of benzene. Very little is excreted in their unchanged form, either through the lungs or the kidneys. Virtually all are converted to their respective toluic acids, conjugated with glycine and excreted as methyl hippuric (toluric) acids. A small amount of xylenols can also be found (37).

In common with the alkenes already discussed, the aromatic hydrocarbons undergo oxidation by the hepatic mixed function oxygenases to form highly reactive arene oxides. They may isomerize readily to phenols, may be converted by epoxide hydratase to dihydrodiols or may form glutathione conjugates (30). The possibilities for benzene are shown below:



Similar labile epoxides are intermediates in the metabolism of toluene and xylene.

Toxicity

Since several million workers in the United States are exposed to these aromatic hydrocarbons, they have been extensively investigated and are the subjects of recent reviews (24, 25, 27). The acute toxicities are summarized in Table 9.

Table 9. Acute toxicity of aromatic hydrocarbons.

Compound	Animal	Route	LD_{50} (mg/kg)	Reference
Benzene	Mouse	Intraperitoneal	468	26
	Rat	Inhalation	10,000 ppm/7 hr.	26
	Rat	Oral	930	7
	Rat (young)	Oral	3400	16
	Rat (old)	Oral	5600	16
Toluene	Mouse	Inhalation	5300 ppm	26
	Rat	Oral	5000	26
	Rat	Intraperitoneal	1640	26
Xylene	Rat	Oral	4300-5000	26

Benzene

Although deaths and severe central nervous disturbances have been reported from acute exposure to high concentrations of benzene in air (approximately 2.5 percent) (27), it is the chronic exposure to moderate levels of the compound that has aroused the greatest concern. Large amounts of the compound are clearly capable of depressing bone marrow activity. Exposure to benzene in a contaminated workroom atmosphere is well known to lead to blood dyscrasias, particularly to a reduction in the leukocyte count, and in some cases, to aplastic anemia.

Various types of leukemia have been reported to result from chronic benzene exposure and possibly to arise preferentially in those persons developing aplastic anemia. Blood dyscrasias and leukemias have also been noted among patients receiving certain drugs such as phenylbutazone, chloramphenicol and some sulfonamides. However, the evidence of an association of leukemias with blood dyscrasias in these patients and those exposed to benzene is equivocal and is based mainly on unconvincing case reports.

In an extensive epidemiological survey, Aksoy et al. (1) in 1974 reported a correlation between benzene exposure and leukemia. Among 28,500 shoemakers in Istanbul, 26 patients with acute or preleukemia were detected during a 7-year period for an annual incidence of 13 per 100,000, contrasted with 6 per 100,000 among the general population. The maximum benzene concentrations to which these workers were exposed were 210 to 650 ppm. The mean duration of exposure was 9.7 years. Thorpe (41), on the other hand, reporting the same year, failed to detect an increased incidence of leukemia among 38,000 petroleum workers who were at least potentially exposed to benzene. A recent report by the National Institute of Occupational Safety and Health (14) compared the deaths from leukemia among white, male employees exposed to benzene in a large rubber plant, with those in a control population during the same time period. Seven deaths among 748 men were recorded in the former group, or approximately five times the incidence among the controls. Largely on the basis of this report, the Occupational Safety and Health Administration on May 27, 1977 proposed a temporary emergency standard reducing the permissible workroom levels of benzene from 10 to 1 ppm (31). On June 8, 1977, the Environmental Protection Agency added benzene to its list of hazardous air pollutants (8). These studies have not eliminated the possibility that agents other than benzene may be responsible for leukemogenesis in the large study populations.

Stable or unstable chromosomal aberrations in man may be produced by high levels of benzene (several hundred ppm) (27). No correlation has been demonstrated between the persistence of these changes and the degree of benzene exposures.

Despite its status as a suspect leukemogen in man, attempts to induce leukemia in animals by benzene exposure have been unsuccessful (42). Benzene has frequently been used in skin painting experiments as a solvent without producing tumors. Because of this inability to induce leukemia in animals, Ward et al. (42) speculate that benzene may induce leukemia only in highly sensitive persons or by synergistic action with other environmental agents.

No developmental malformations were detected when pregnant mice were exposed continuously to doses ranging from 1 to 670 mg per m^3 of benzene vapor, but at the highest doses, the number of fetuses per litter was reduced (36).

The possibility that benzene may be a leukemogenic agent in man cannot be excluded on present evidence. After a recent critical review of the relevant data, the Committee on Toxicology (27) of the National Research Council concluded that benzene must be considered a suspect leukemogen but that more definitive data are required for an accurate assessment of its effects.

Toluene

Workmen's exposure to toluene is almost exclusively through the lungs or skin, so that very limited data are available on its oral toxicity. As shown in Table 9 the lethal dose by this route in the rat is 5000 mg per kg. In animals, the toxic effects are primarily on the central nervous system and range from light narcosis to prostration, depending upon the extent of exposure. No effects could be confirmed on the blood or blood-forming organs when toluene was administered either by inhalation or percutaneously, even at levels that produced marked central nervous effects.

In man, too, the acute effects are largely on the central nervous system (5). They are narcotic and result in muscular weakness, incoordination and mental confusion (24).

The TLV for workroom exposure is 100 ppm (375 mg per m^3). After chronic exposure to atmospheric concentrations of 100 to 1100 ppm for 2 weeks to 5 years, enlarged livers and macrocytosis were noted in about 20 percent of the subjects (11). Chronic exposure to approximately 200 ppm for 3 to 15 years produced no chromosomal changes in the lymphocytes (9). Various reports in the early literature report toxicity to blood and blood-forming organs by toluene. However, since industrial-grade toluene contains significant amounts of benzene, many of the reported effects may be attributable to this contaminant.

Xylene

The acute toxicity of xylene in animals approximates that of toluene (Table 9). Inhalation for 4 hours of mixed xylenes by rats and dogs in concentrations exceeding 500 ppm caused no apparent ill effects (4). Guinea pigs exposed to 300 ppm for 4 hours daily, 6 days per week for 2 months showed only slight liver and lung effects (38). Recent investigations with both dogs and rats revealed no gross or microscopic pathology nor any hematological disturbances, even with exposures as high as 805 ppm for 6 hours per day, 5 days per week for 13 weeks (4). Intraperitoneal injection of xylene into rats caused liver necrosis and diffuse nephritis (2). Liver and kidney damage has also been reported in man after inhalation of sufficient xylene to cause unconsciousness (23). However, the victims recovered fully and there is no evidence in the literature of irreversible damage to either kidney or liver (25).

Commercial xylene contains varying amounts of the ortho-, meta-, and para-isomers as well as other aromatic and aliphatic hydrocarbons, thiophene, pyridine and phenol. Consequently, many reports on the toxicity of xylene are unreliable since exposures were rarely to a pure preparation. Thus, even though early reports attributed a myelotoxic effect to xylene, it is now believed that xylene poses no threat to the blood and blood-forming organs. Its toxic effects are very similar to those of toluene and are reflected primarily in the form of headache, lassitude, fatigue and irritability, together with minor gastrointestinal symptoms (10). The TLV of xylene is 100 ppm or 435 mg per m^3.

Berenblum (3) painted the skin of white mice with xylene alone and with 3, 4 benzpyrene and xylene and concluded that xylene was neither carcinogenic nor co-carcinogenic. Pound (35) reported an increased incidence of skin tumors in mice pretreated with xylene and exposed to ultraviolet light, but he attributed this increase to the hyperplasia induced in the skin, rather than to carcinogenic properties of the xylene. Pre-treatment with croton oil or acetic acid caused similar increases in skin tumors.

Russian workers (17) investigated possible embryotoxic effects of xylene by exposing pregnant rats to para-xylene (115 ppm) continuously for 20 days. No teratogenic effects were noted.

Discussion

The presence of toluene and xylene in the irradiated beef would seem little cause for concern. Xylene does not appear to be a radiolytic

product, and the concentration of toluene in thermally sterilized beef is equal to or greater than that in the irradiated samples. Both are widely distributed in other foods, often in considerably greater amounts than in beef. The amount of benzene increases slightly upon irradiation, reaching a level of 15 to 19 μg per kg after exposure to 56 kGy (5.6 megarads). This would represent a daily intake from irradiated beef of approximately 2 μg.

Benzene has been detected in nonirradiated beef by numerous workers, but comparison with irradiated samples is made difficult by the lack of quantitative data. The only reported value is 2 ppb (6.4 μg per m^3) in the head space of canned beef (33). In semiquantitative studies the amount of benzene has been characterized as "large" in canned beef stew (6, 34), and boiled beef (6, 12). It has also been detected in roast beef (22) as well as in a score of other foods.

Unavoidable absorption from air and water supplies also contribute significantly to the daily intake of benzene. The average atmospheric concentration in metropolitan areas is about 45 μg per m^3 and may increase several fold during peak traffic periods. Body retention has been shown to be 25 to 30 percent (28, 13) of the total inhaled or about 100 μg daily. This is approximately 40 times the daily intake from irradiated beef. The recently imposed emergency measure for workroom atmospheres reduces the permissible levels from 10 to 1 ppm. Even at this sharply reduced limit, the average workman (after his 8 hour stint) would retain about 2.5 to 3.0 mg benzene or more than 1000 times that consumed in irradiated beef.

The Committee believed that a small addition of benzene from irradiated beef contributes only a trivial increment to the normal body burden and is unlikely to increase significantly whatever hazard exists from other sources.

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B. OXYGEN-CONTAINING COMPOUNDS

1. Alcohols

Methanol and ethanol, the simplest of the primary alcohols have been detected in both irradiated and nonirradiated beef (Table 10). The concentrations of methanol in the thermally sterilized samples are greater than those in the irradiated beef. Ethanol, on the other hand, increases significantly with irradiation.

Occurrence

Methanol and ethanol are produced in huge quantities for a variety of industrial, medicinal and household purposes. Methanol has been detected in water supplies of six of ten cities tested (3) and, as shown in Table 10, is a normal constituent of many meats, beverages, fruits, vegetables and dairy products. It is also found normally in the breath, blood and urine of man and is considerably elevated after ethanol consumption (7).

Ethanol can result from the natural or deliberate fermentation of numerous carbohydrate foods. Millions of gallons are consumed annually in numerous alcoholic beverages. Even those persons who conscientiously abstain from such beverages cannot avoid the ingestion of significant amounts of ethanol from other sources. As is apparent from Table 10, milligram quantities or more can easily be ingested daily from fruits, fruit juices, cheeses and various vegetables.

Metabolism

Because of its simple structure and high solubility, methanol is rapidly absorbed from the intestinal tract and distributed evenly in body water. Substantial amounts are eliminated through the lungs but its major metabolic pathway is through formaldehyde and formic acid to carbon dioxide and water. A small amount may escape conversion and be excreted unchanged in the urine. Small amounts of its glucuronide and of formic acid can also be found in the urine (11). Although it is generally assumed that formaldehyde is the initial oxidation product of methanol, it has not been detected in the blood and urine, presumably because of its rapid conversion to formic acid. Keeser (4) has found

Table 10. Distribution of methanol and ethanol.*

	Irradiated beef µg/kg		Thermally sterilized beef µg/kg		Frozen beef control µg/kg		Atmosphere µg/m³	Water µg/l	Food µg/kg
	Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked			
Methanol	16	20	23	40	41	0	Near production plant - 18-33 Simulated spacecraft - 125 Incinerator - 500-4000	Detected in over half of city waters tested concentrations not reported	Passion fruit juice - 4000; Rum, Jamaican - 80; reported in over 50 foods; meats, beverages, fruit, dairy products, vegetables
Ethanol	75	123	9	15	18	0	Simulated spacecraft - 46	5.0 (highest reported in U.S. water)	Apple essence - 15,000; banana - 5,000; cheese (cheddar) - 620,000; cherry - 55,000; cucumber - 200-2000; grapefruit juice - 400,000 - 660,000; passion fruit juice - 100,000; pineapple - 60,500; raspberry - 10-100; strawberry - 1,510; vinegar - 1,650,000 (found in over 50 foods)

*See Table 5, footnote a.

it in the aqueous and vitreous humors of rabbits poisoned with methanol. Formaldehyde is a powerful inhibitor of retinal respiration (5) and the blindness often resulting from methanol consumption is believed attributable to this action.

Ethanol, too, is readily absorbed from the gastrointestinal tract. Some is excreted through the lungs and kidneys but most is metabolized to carbon dioxide and water. It is first oxidized in the liver to acetaldehyde, which is then converted to acetate or to its activated form, acetylcoenzyme A, which can enter the general metabolic pool of two carbon fragments.

Several enzyme systems are capable of oxidizing methanol and ethanol and their respective roles have not been entirely elucidated. Alcohol dehydrogenase is primarily responsible for the oxidation of ethanol and probably for that of methanol as well (2). Catalase (10) and a microsomal oxidizing system in the liver (7) may also participate under certain conditions or in certain animal species.

The subsequent oxidation of the acetaldehyde produced from ethanol is accomplished by acetaldehyde dehydrogenase with possible contributions from xanthine and aldehyde oxidases. Both of these enzymes rapidly metabolize acetaldehyde and other aliphatic aldehydes in vitro. However, only traces of xanthine oxidase are present in the human liver (9), so its significance in normal metabolism is questionable.

Toxicity

Although methanol or ethanol poisoning usually results from an overly generous consumption of alcoholic beverages, both compounds are sufficiently volatile to pose potential hazards to workmen exposed to their fumes. Consequently, threshold limit values have been established for workroom environments in the U.S. For ethanol, the TLV is 1000 ppm (1900 mg per m^3), and for methanol it is 200 ppm (260 mg per m^3) (1).

The relative toxicity of these alcohols by different routes in different animals can be judged from representative values taken from the Registry of Toxic Effects of Chemical Substances (8) (Table II).

Table 11. Toxicity of methanol and ethanol.

Substance	Animal	Route	LD_{50} mg/kg
Methanol	Mouse	Subcutaneous	9800
	Monkey	Inhalation	1000 (ppm)
Ethanol	Mouse	Subcutaneous	8285
	Rat	Intravenous	1440
		Intravenous	1973
	Rabbit	Oral	6300
	Guinea pig	Oral	5560

Discussion

The ethanol in a single beer or cocktail or glass of wine would equal that present in many tons of irradiated beef, so that the potential contribution of irradiated beef is trivial and can be disregarded as a health hazard. Virtually every category of foodstuffs -- fruits, vegetables, dairy products, juices, -- contains significant quantities of ethanol.

Methanol also is widely distributed among foodstuffs and consumed in significant amounts. It has been detected in the water supplies of six of ten American cities where such analyses were made. While data are not available on man's normal intake of methanol, it is believed to be far higher than the 3 to 4 µg that would be contributed daily from irradiated beef.

The Committee believes the amounts of these alcohols consumed from irradiated beef do not constitute a hazard to health.

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2. Aldehydes

Occurrence

A number of aldehydes were detected in the irradiated uncooked beef samples (Table 12). Apart from 2-methyl pentanal, all were relatively long chain compounds ranging from 11 to 18 carbon atoms. The total aldehyde content was approximately 0.8 mg per kg of beef. Almost half of this amount came from octadecenal and presumably arose from oleic acid, a major constituent of beef fat. The concentrations of the remaining aldehydes varied from 0.011 to 0.127 mg per kg of beef.

As is evident from Table 12, the free fatty aldehydes are widely distributed in nature. They have been identified in yeast (7), bacteria (5), fruit (9), vegetables (9) and in various mammalian tissues (6, 12, 14, 26). Some are natural flavoring substances and are present in relatively large amounts in certain foods, especially in citrus fruits. In fact, the longer chain aldehydes are the major flavor constitutents of most citrus oils (2). Thus, a kilogram of orange oil contains 140 to 4500 mg undecanal (17), 760 to 4600 mg dodecanal (2, 17) and 130 to 1240 mg tetradecanal (2). Hexadecanal has also been identified as one of the major aldehydes in orange oil, although its concentration was not reported (2).

Dodecanal and tetradecanal have been used as fragrances for approximately 50 years and undecanal since the 1940's. Approximately 20,000 pounds each of undecanal and dodecanal and 2000 pounds of tetradecanal are used annually in soaps, detergents, creams, lotions and perfumes.

The fatty aldehydes have also been identified as naturally occurring components in mammalian lipids, where they occur both in free and in bound forms. Gilbertson et al. (13) have isolated from the hearts of rat, dog and cow all the aldehydes found in irradiated beef except for 2-methyl pentanal. The total free aldehyde concentrations were approximately 20 to 40 mg per kg of fresh heart muscle. Hexadecanal and octadecanal were the principal aldehydes present, with the former accounting for roughly half of the total. Only trace amounts of undecanal and dodecanal were detected. More recently, Ferrell and Radloff (8) measured the free fatty aldehydes (C_8 to C_{18}) in normal and infarcted hearts. In the apparently normal hearts of two men, 46 and 72 years old respectively, they found 1.91 and 9.14 μ moles of aldehydes per 100 mg lipid (21). The principal free aldehydes detected were dodecanal, hexadecanal, heptadecanal, octadecanal and octadecenal. The infarcted hearts showed increased aldehyde concentrations, especially of tetradecanal. Free aldehydes have also been found in rat brain (26), human serum (12) and mouse liver (6).

Table 12. Distribution of aldehydes found in irradiated beef.*

Compound	Irradiated beef uncooked µg/kg	Other foods µg/kg
2-Methyl pentanal	11	Found in beef, chicken, coffee, crisp bread, garlic, meat, onion, peanut, tomato, vinegar
Undecanal	76	Bilberry - 50; oil, orange - 140,000-4,500,000; oil, roasted peanut - 150; also found in fruit, meat, dairy products
Dodecanal	63	Bilberry - 20; milk, dry - 5; beef, cooked - 100; egg - 7400; citrus oils - 760,000-4,600,000; tomato - 7710; oil, roasted peanut - 93; found in approximately 20 foods: dairy, fruit meat, beverages
Tetradecanal	54	Bilberry - 20; citrus oils - 130,000 - 1,240,000; oil, roasted peanut - 230; also found in grape, lemon
Pentadecanal	46	
Hexadecanal	127	Found in beef, bilberry, chicken, citrus fruits, cranberry, pork
Octadecanal	30	Found in beef, chicken, pork
Hexadecenal	33	Oil, roasted peanut - 63
Octadecenal	398	

*None of these aldehydes were found in the thermally sterilized, frozen control or raw beef samples.

Metabolism

It is generally stated that aldehydes are readily oxidized in the animal body to the corresponding acids and converted by beta oxidation to carbon dioxide and water (27). This oxidation is catalyzed by three enzyme systems: aldehyde dehydrogenase (20), aldehyde oxidase (22) and xanthine oxidase (23). Although this pathway is well documented, there is growing evidence that reduction of the aldehyde to its alcohol also occurs and may actually be the favored route, especially for xenobiotic aldehydes and ketones. Kessler and Ferrell (16) isolated an alcohol dehydrogenase from the supernatant fraction of mouse liver homogenate capable of reducing aldehydes ranging from acetaldehyde to octadecanal. Bachur (1) has recently compiled a list of carbonyl-reducing enzymes whose characteristics are remarkably similar. All these enzymes are found in the cytoplasm and are widely distributed in tissues. Bachur has termed this ubiquitous class of enzymes "cytoplasmic aldo-keto reductases."

Toxicity

Toxicity data on these aldehydes are disappointingly sparse. Oral rat LD_{50} values for 2-methyl pentanal (25), undecanal (24), dodecanal (3), and tetradecanal (18) are all greater than 5 g per kg body weight. Rats survived inhalation of 8000 ppm of 2-methyl pentanal for 4 hours with no deaths (25). After intraperitoneal injection of tetradecanal, hexadecanal and octadecanal into mice, the LD_{50}s were 2.2, 2.0 and 1.3 g per kg body weight respectively (11). Data on oral ingestion are available only for tetradecanal which was fed to mice at levels of 166 mg per kg for 130 days with no apparent toxic effect (11). No data have been found on the toxicity of hexadecenal and octadecenal.

Discussion

The long chain aldehydes are important flavor components of fruits and other foods. With the exception of pentadecanal and octadecenal, each of the compounds found in the irradiated beef has been reported in other foods and most of them have been detected in cardiac tissue. Those that have been tested have very low toxicities and what is known of their metabolism suggests that these aldehydes are readily converted to innocuous materials. Some of these compounds or their close relatives are utilized by the food industry to simulate the odor and taste of natural foods (15). The Food and Drug Administration (19) sanctions the use of dodecanal and tetradecanal for this purpose as well as several close relatives of undecanal; namely, undecalactone, undecenal, undecanone, undecyl alcohol and undecenyl

acetate (21 CFR 172.515, formerly 21 CFR 121.1164) (19). The Council of Europe (4) has approved undecanal itself as a flavoring adjuvant as well as dodecanal and tetradecanal. Similarly, these three aldehydes have been approved as food flavors by an expert committee for the British Ministry of Agriculture (10). The acceptable daily intakes are roughly 1000 to 10,000 times the amounts of the respective aldehydes from the irradiated beef.

The Committee does not believe the amounts of the various aldehydes found in irradiated beef constitute a significant increment of hazard to the consumer.

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3. Ketones

Occurrence

The two simplest ketones, acetone and 2-butanone (methyl ethyl ketone) were present in concentrations of 139 and 89 µg per kg respectively in the irradiated beef (Table 13). No other ketones were detected.

Both compounds are widely distributed in nature. Acetone has been detected in virtually every food examined. Its presence has been reported in over 70 foods including beverages, fruits, vegetables and meat. Amounts in excess of 1 mg per kg (1 ppm) have been reported for beer, butter, certain cheeses, milk, eggs, strawberries and other foods. It is found in significant amounts in diesel exhaust (25), in the effluents from wood burning (14) and solid waste incineration (27), in drinking water (8) and in ambient air (10) (Table 13). It normally is found in small amounts in the tissues and fluids of man and other animals. In severe diabetes, when fat is the predominant metabolic substrate, as much as 100 grams per day of acetone, beta hydroxybutyric and acetoacetic acids (ketone bodies) may be produced and excreted. Comparable amounts may also be produced during starvation.

2-Butanone is also a ubiquitous food constituent, found naturally in a variety of fruits, vegetables, meats and dairy products. It is also widely used as a flavoring constituent in certain beverages, ices, candy and baked goods.

Metabolism

Because of its extreme solubility, acetone is readily absorbed into the blood stream after inhalation. Whether inhaled or ingested, acetone is rapidly excreted through the lungs with the kidneys serving as secondary excretory organs (6, 7, 26).

Small amounts are oxidized to carbon dioxide or converted to formate or acetate. Price and Rittenberg (19) administered 1 to 7 mg per kg of labeled acetone to rats and found that about half was exhaled as carbon dioxide within 24 hours. The labeled atom which appeared in a number of compounds, including glycogen, urea and cholesterol, suggested that acetone was split to one or two carbon atoms and utilized in various metabolic cycles.

Recently, Leibman (13) demonstrated that acetone, in common with various other aliphatic and aromatic ketones, can be reduced by the broad

Table 13. Presence of ketones in various media.*

Compound	Irradiated beef μg/kg		Thermally sterilized beef μg/kg		Frozen beef control μg/kg		Atmosphere μg/m³	Water μg/l	Food μg/kg
	Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked			
Acetone	107	139	65	120	3	4	4800 (24 hour average near production plant) Simulated spacecraft - 140 Fireplace - 5,000 - 10,000	1.0 (Seattle) 6.3-9.5 (Connecticut)	Beef, canned - 650; beer - 1400; butter (oil) - 42000, butter (sweet cream) - 130; carrot - 200; cheese (cheddar) - 3500; cheese (blue) - 510; cherry essence - 16000; eggs - 22300; grapefruit juice - 100; ham (cured) - 650; ham (uncured) - 500; milk (dry) 450-1260; milk (whole) 3000; pea - 350; oil (roasted peanut) - 3600; rum, Jamaican - 250; soybean, raw - 1600; strawberry - 1300; whiskey - 200; detected in over 70 foods of all types
2-Butanone	72	89	5	10	5	0	Simulated spacecraft - 590		Beef, canned - 14-110; butter - 160; cheese (cheddar) - 180; eggs - 9600; grapes - 10; lingonberry juice - 6; milk, dry - 15-75; peanut oil - 130; pear - 1000; rum - 30; detected in almost 60 foods

*See Table 5, footnote a.

category of liver and kidney enzymes which Bachur (3) has termed the cytoplasmic aldo-keto reductases. However, in contrast with other aldehydes and ketones, only a small fraction of absorbed acetone is reduced to alcohol and excreted as its glucuronide (26).

Little can be added concerning the metabolic pathways of 2-butanone, the other ketone detected in irradiated beef. Variations from acetone seem related to differences in physical properties of the two ketones. Since 2-butanone is somewhat less volatile than acetone, less is excreted unchanged through the lungs and more is subjected to enzymatic action (21). It appears that butanone can be reduced to a secondary alcohol by the liver and kidney cytoplasmic reductases described above (13). DiVincenzo et al. (5) also detected 3-hydroxy-2 butanone and 2, 3-butanediol after butanone administration indicating that some of the compound follows an oxidative pathway.

Toxicity

Both acetone and 2-butanone are generally considered to be relatively nontoxic. The Joint FAC/WHO Expert Committee on Food Additives (11) has approved the use of acetone as a solvent in accordance with "good manufacturing practices" and states that "many years of human industrial experience have shown no evidence of organ damage." The Food and Drug Administration (17) also permits the use of 2-butanone in foods as a synthetic flavoring substance (21 CFR 172.515, formerly 21 CFR 121.1164), as does the British Ministry of Agriculture (9) and the Council of Europe (4). The latter permission has been on a temporary basis since 1973, pending additional medium term toxicity studies on a sensitive species but no study of this type has been reported. McCann et al. (15) reported that acetone was nonmutagenic in Salmonella typhimurium.

For inhalation, the threshold limit values adopted by the American Conference of Governmental Industrial Hygienists for workroom atmosphere (2) are 1000 ppm (2400 mg per m^3) for acetone and 200 ppm (590 mg per m^3) for butanone. Oglesby et al. (18) stated that a study of thousands of mill workers exposed to acetone revealed at most, only minor irritation of eyes and nose at levels of 2500 to 3000 ppm.

2-Butanone is widely used as an industrial solvent and although workers frequently complain of its objectionable odor, it has been stated that exposure to 700 ppm in the air gave no evidence of permanent ill effects (7). Dermatoses are common among workers handling butanone and numbness of fingers and arms were reported by some exposed to 300 to 600 ppm (22). The question of possible neuropathy was reconsidered when

a recent outbreak occurred among workers in a color-print and plastic-coated fabric plant exposed to 2-hexanone, a close relative of butanone (1). Saida and co-workers (20) produced extensive peripheral nerve changes in rats exposed to hexanone but none upon continuous exposure to butanone at concentrations of 1125 ppm for up to 55 days. Similar results were obtained with cats (24). DiVincenzo et al. (5) attributed the toxicity of the hexanone to the enzymatic formation of 2, 5-hexanedione, which produced a marked peripheral neuropathy in rats. However, when rats were exposed to the combined vapor at a ratio of one part hexanone to five parts of butanone (225:1125 ppm) a marked potentiation of the peripheral neurotoxicity was observed (20).

Lethal concentrations by different routes in different species are summarized in Table 14.

Table 14. Toxicity of ketones.

Compound	Animal	Route	LD_{50}	LD_{100}	Reference
Acetone	Mouse	Inhalation		46000 ppm	11
		Inhalation		3200 ppm	23
		Oral	10,700 mg/kg		23
		Oral	9,700 mg/kg		11
		Intravenous		4 ml/kg	11
		Intraperitoneal	1297 mg/kg		16
	Rabbit	Oral	5300 mg/kg		16
		Intragastric	5340 mg/kg		11
		Intravenous		6-8 ml/kg	11
		Percutaneous	>20 ml/kg		23
	Dog	Oral	8000 mg/kg		11
2-Butanone	Mouse	Intraperitoneal	616 mg/kg		16
	Rat	Oral	3400 mg/kg		16
		Oral	2730-5490 mg/kg		11
		Oral	6860 ml/kg		23
		Inhalation	8000 ppm/8 hr.		23
	Rabbit	Percutaneous	>10 ml/kg		23

Discussion

Acetone and butanone have been detected in scores of foodstuffs. In some commonly consumed foods, their concentrations exceed by a large margin the quantities found in irradiated beef. Both have been approved by official bodies, including the Food and Drug Administration for use as a food extractant or additive. Both are widely used in industry without evidence of chronic human toxicity. Their metabolic products pose no apparent hazard. For these reasons, the Committee believes that the amounts of acetone and butanone present in irradiated beef can be consumed without harm.

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C. SULFUR-CONTAINING COMPOUNDS

Occurrence

Five sulfur-containing compounds -- four sulfides and one thiol -- were detected in irradiated beef: carbonyl sulfide, dimethyl disulfide, dimethyl sulfide, ethane thiol and hydrogen sulfide (Table 15). All were found in both cooked and uncooked samples. The thermally sterilized samples contained considerably more carbonyl sulfide than did the irradiated specimens. No ethane thiol or dimethyl sulfide was detected in the nonirradiated beef, while the amounts of hydrogen sulfide and dimethyl disulfide were approximately the same in irradiated and thermally sterilized samples.

Sulfur compounds originate from many natural and anthropogenic sources. Significant amounts of hydrogen sulfide are constantly added to the atmosphere from volcanic and geothermal activity, from anaerobic bacterial action and from various industrial processes. Natural gas is rich in hydrogen sulfide and the processing techniques to remove this contaminant give rise to considerable amounts of carbonyl sulfide. Carbonyl sulfide is also generated when fossil fuels containing sulfur are burned. In man and other animals, hydrogen sulfide is liberated in the intestinal tract and is a readily detectable component of flatus (9) and fecal material. In addition to these sources, hydrogen sulfide, carbonyl sulfide and other sulfur containing compounds are also found in numerous foods, as shown in Table 15.

Sulfur-containing compounds are present in a wide variety of foodstuffs and are especially prominent in many vegetables, meats and roasted products such as coffee, cocoa and peanuts. Volatile sulfur compounds were detected in 21 of 23 varieties of vegetables investigated (7). The broadest distribution was noted for hydrogen sulfide, dimethyl sulfide and dimethyl disulfide, with a somewhat more limited occurrence of ethane thiol. Carbonyl sulfide was found in large amounts in horseradish and was readily detectable in other vegetables and meats.

In general, the concentration of these compounds increases significantly after heating. Dimethyl disulfide has been reported in almost all cooked vegetables (13). It represents, for example, over 25 percent of the total volatiles from fresh cabbage and almost 40 percent of those from cooked samples (10). It is also evident after heating beef, when it may reach levels of 100 μg per kg and contribute to the off-flavor of overcooked meat (19). Hydrogen sulfide is a major contributor to the flavor and off-flavor of cooked

Table 15. Distribution of sulfur compounds.*

Compound	Irradiated beef µg/kg		Thermally sterilized beef µg/kg		Frozen beef control µg/kg		Atmosphere µg/m³	Foods µg/kg
	Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked		
Carbonyl sulfide	2	2	22	75	0	0	183 (Los Angeles)	Horse radish - 12000; found in chicken, cabbage, parsley
Dimethyl disulfide	3	4	7	13	1	1		Haddock (stored 14 days) - 150,000; cheddar cheese - 70,000; beef (cooked) - 100; eggs - 7400; also found in: onion, garlic, peas, cabbage, rutabaga, potato, beans, cauliflower, tomato, sprouts
Dimethyl sulfide	4	6	0	0	0	0		Haddock (stored 14 days) 200,000; cheddar cheese - 1000; Baltic herring - > 1000; found in: canned beef, onion, leek, garlic, pea, beans, cabbage, cauliflower, rutabaga, carrot, sprouts, potato, celery, parsnip, tomato
Ethane thiol	7	10	0	0	0	0	Simulated spacecraft - 35	Beef, canned - 170-290; carrot, canned - 50; fish protein concentrate - 37; potato, boiled - 100-200; also found in: onion, leek, peas, cauliflower, parsnip
Hydrogen sulfide	2	2	1	5	0	0	1-20 140-1400 (flatus)	Beef, broth - 6000-8000; beef, canned - 1100 - 2900; beer - 110; broccoli - 10,000; cabbage - 300,000 - 790,000; cauliflower - 20,000; cheese cheddar - 3-50,000; oryzae - 20; gouda - 48; trappist - 1900; chicken, boiled - 580-730; chicken, broth - 35; chicken, cooked - 180-1000; corn - 14-131; eggs, boiled - 178; fish protein concentrate - 850; grapefruit juice - 900; orange juice - 1600; potato, boiled - 150-525

*See Table 5, footnote a.

meats, fish, certain vegetables such as broccoli and cabbage, and especially of eggs.

The origin of these compounds has not been extensively investigated, but methionine is generally believed to be their major precursor (2, 3), especially for dimethyl sulfide and dimethyl disulfide. The Maillard reactions in heat-processed foods give rise to various alkyl thiols and carbonyl sulfide (13) while hydrogen sulfide can arise from various sulfur-containing amino acids, peptides and proteins and from thiamine. Cysteine, however, appears to be its chief precursor.

Metabolism

Surprisingly few studies have been conducted on the fate of the simple sulfur volatiles identified in the irradiated beef. By analogy with the body's treatment of known sulfur xenobiotics, oxidation would appear to be the preferred pathway of metabolism.

Hydrogen sulfide is very susceptible to oxidation. It is oxidized so readily that its reported levels in the atmosphere may reflect artifically low values resulting from oxidation during sampling and analysis (8). Although documentation could not be found, it seems likely that hydrogen sulfide is also oxidized in the body. In any event, the simplest organic sulfide -- dimethyl sulfide -- has been shown to undergo such oxidation, first to the sulfoxide (16) and then to the sulfone (6).

The disulfides, on the other hand, are first reduced to the corresponding mercaptans by a nonspecific nucleotide-dependent disulfide reductase (15). The resulting mercaptans maybe partially eliminated, unchanged in the expired air and urine, but the bulk is oxidized as described above and excreted in the urine as its sulfone (14) or as inorganic sulfate (17). Ethane thiol undergoes a similar transformation, being partially excreted unchanged in the breath and urine and partially as the sulfone and inorganic sulfate in the urine. Ethane thiol may also be methylated by S-methyl transferase to produce its S-methyl analogue (18). In addition, thiols undergo conjugation with glucuronic acid (17) although this has not yet been demonstrated with ethane thiol.

No reports could be found on the metabolism of carbonyl sulfide. Since it is readily hydrolyzed by water to hydrogen sulfide and carbon dioxide, its fate in the body would presumably be the same as these products.

Toxicity

The ingestion of volatile sulfur compounds is largely self-limiting because of their strong odor and taste. Small amounts may be

necessary to impart a desirable, characteristic flavor to the food, but excessive quantities discourage consumption by all except those with highly insensitive or idiosyncratic tastes. The quantities detected in the irradiated beef fall well within the range naturally present in many foods. The Council of Europe (4) has approved the addition of several of these compounds as flavoring adjuncts. The acceptable daily intake for dimethyl sulfide has been set by this group at 1.5 ppm of ingested food (about 1.5 to 2.5 mg per day) and for ethane thiol at 1 ppm (about 1.0 to 1.5 mg per day). No level has been set for hydrogen sulfide, presumably because of the self limiting aspect mentioned above. British authorities have recommended approval of hydrogen sulfide, dimethyl sulfide, dimethyl disulfide and ethane thiol as food flavoring adjuvants (5). The Food and Drug Administration imposes no limit in its approval of dimethyl sulfide (21 CFR 172.515, formerly 21 CFR 121.1164) as a synthetic flavoring substance that may be safely used in foods (12).

The threshold limit value for workroom atmospheres has been set at 0.5 ppm (1 mg per m^3) for ethane thiol and at 10 ppm (15 mg per m^3) for hydrogen sulfide (1). The acute toxicities of these compounds are summarized in Table 16, constructed from data collected by the National Institute for Occupational Safety and Health (11). Hydrogen sulfide in high concentrations acts directly upon the nervous system causing paralysis of the respiratory center and olfactory system. It also decreases the oxygen carrying capacity of hemoglobin by the formation of sulfhemoglobin. Little is known of the acute effects of the other sulfur-containing compounds.

Table 16. Toxicity of sulfur compounds.

Compound	Animal	Route	LD_{50}
Dimethyl sulfide	Mouse	Oral	3700 mg/kg
	Rat	Oral	535 mg/kg
Ethane thiol	Mouse	Inhalation	2700 mg/kg
	Rat	Intraperitoneal	450 mg/kg
		Inhalation	4420 ppm/4 hr
		Oral	682 mg/kg
Hydrogen sulfide	Mouse	Inhalation	683 ppm/1 hr
	Rat	Inhalation	713 ppm/1 hr

Discussion

The amounts of the sulfur-containing compounds in irradiated beef are extremely small, in no case exceeding 10μg per kg. Three of the five compounds (carbonyl sulfide, dimethyl disulfide and hydrogen sulfide), were more abundant in the thermally sterilized than in the irradiated samples. Each (except carbonyl sulfide) has been detected in numerous foods and in every case where quantitative analysis has been performed the quantity in meat, fish, eggs, fruits and vegetables is far greater than that in irradiated beef. Most of those compounds have been approved by official bodies as flavoring adjuvants at levels several orders of magnitude greater than their concentrations in irradiated beef.

The Committee believes the concentrations of sulfur-containing compounds in irradiated beef are trivial and pose no hazard to the consumer.

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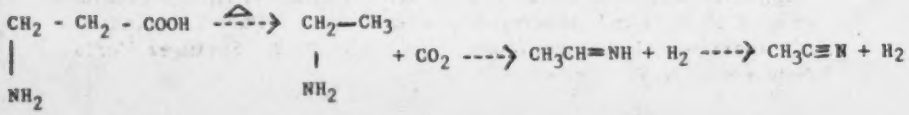
D. NITROGEN-CONTAINING COMPOUNDS

Occurrence

Acetonitrile was the only nitrogen containing organic volatile detected in the irradiated beef. It was present in both the cooked and uncooked irradiated samples (Table 17). The concentrations did not differ significantly from those in the frozen controls and were considerably less than those in the thermally sterilized beef. This suggests that acetonitrile is not a radiolytic product, a suggestion strengthened by the observation that nitriles can be produced from amino acids at conventional cooking temperatures.

No report could be found listing acetonitrile as a normal constituent of food. However, Vollmin and colleagues (8) have shown that nitriles are produced in abundance when amino acids are subjected to high temperatures. Acetonitrile was a major product when the following amino acids were heated to 700° C: glycine, alanine, proline, serine, cysteine, methionine, aspartic acid, ornithine and gamma amino butyric acid. Lien and Nawar (4) using milder treatments, detected the formation of acetonitrile when beta alanine was heated at 200° C in vacuo. The compound apparently resulted from successive decarboxylation and dehydrogenation as follows:



Lien and Nawar also demonstrated that triglycerides and amino acids interact readily to produce secondary amides which hydrolyze to form nitriles.

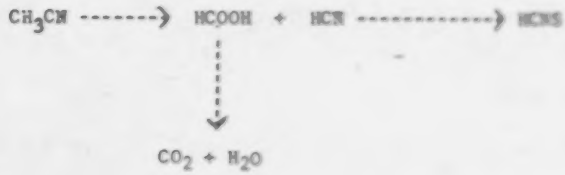
Acetonitrile has been identified in cigarette smoke (2) and in the urine of smokers (5). About one mg of acetonitrile is produced from the smoke of a single cigarette. The average urinary excretion among smokers was more than 100 µg per liter with heavy smokers excreting twice this amount. The highest value detected among nonsmokers was less than 10 µg per liter of urine.

Table 17. Acetonitrile in beef.

Irradiated		Thermally Sterilized		Frozen Control	
cooked	uncooked	cooked	uncooked	cooked	uncooked
μg/kg		μg/kg		μg/kg	
3	1	21 -	57	6	3

Metabolism

The alkyl cyanides (e.g., acetonitrile) are hydrolyzed to hydrocyanic acid and a corresponding acid with one less carbon atom. The cyanide is converted to thiocyanate which is excreted unchanged, while the acid is metabolized through normal metabolic pathways to carbon dioxide and water (9).



Toxicity

The acute toxicity of acetonitrile is summarized in Table 18. It was the least toxic of all alkyl nitriles tested in mice and rabbits (9). Pozzani et al. (6) subjected rats to acetonitrile vapor for seven hours daily for 90 days. No deaths were encountered even at levels of 655 ppm, but two monkeys exposed to this concentration died within 23 and 51 days respectively. One monkey inhaling 330 ppm survived the 91 day test period as did three dogs. No gross pathology was evident but histological examination revealed focal emphysema and diffuse proliferation of alveolar septa.

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The TLV is 40 ppm (70 mg per m^3) (1). This value seems based primarily on the study by Pozzani et al. (6) on human subjects who inhaled the vapor at this concentration for 4 hours. Two of the three subjects reported no adverse effects. No cyanide could be detected in their blood nor was there any increase in the level of urinary thiocyanate. The third subject experienced a slight tightness and a sensation of coolness in the chest after the exposure. There was a slight increase in his urinary thiocyanate.

Table 18. Acute toxicity of acetonitrile.

Animal	Route	Minimum Lethal Dose	LD_{50}	Reference
Mouse	Intraperitoneal		250 mg/kg	6
Rat	Intragastric		1.7-8.5 g/kg	6
			3.8 g/kg	7
	Subcutaneous		5 ml/kg	3
	Intraperitoneal		0.95-5.62 g/kg	6
	Intravenous (portal)		0.71 ml/kg	6
	Intravenous (tail)		1.68 ml/kg	6
	Inhalation	8000 ppm/4 hr.	16000 ppm/4 hr	6
	Percutaneous		1.25 ml/kg	6
			5.0 ml/kg	1
	Inhalation		2800 ppm/4 hr	6
Guinea pig	Inhalation		5655 ppm/4 hr	6

Discussion

Acetonitrile is a nonradiolytic product. The minute amounts in irradiated beef are no greater than in frozen controls, and are considerably less than in thermally sterilized samples. Evidence also points to its rapid hydrolysis in the body. The Committee concludes that ingestion of acetonitrile in the amounts found in irradiated beef should have no harmful effects.

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E. HALOGEN-CONTAINING COMPOUNDS

Tetrachloroethylene

Occurrence

Tetrachloroethylene (perchloroethylene) was the only organochlorine compound detected in the irradiated beef in concentrations sufficient to permit quantitative analysis ($\gtrsim$ 1 ppb). Its concentration (8 to 11 µg per kg) (Table 1) was not significantly different from the amounts detected in the nonirradiated samples, nor did it increase with higher irradiation doses.

Because of its nonflammability and its excellent solvent ability, tetrachloroethylene is found in a number of consumer and industrial products. It is the leading dry cleaning solvent in the U.S.; it is used extensively to degrease metals; it serves as a solvent for silicones; it is an intermediate in the synthesis of fluorocarbons and at one time it was used extensively as a human and veterinary antihelminthic. Its production on a world-wide basis exceeds one million tons per year, with approximately one-third of this amount produced in the United States.

As is evident from Table 19, it has been detected above the North Atlantic and in the air of rural and metropolitan areas. It is present in the ocean waters, in rivers and in municipal water supplies; in aquatic organisms, fish, birds, mammals and man; in fruits, vegetables, beverages and dairy products. It was detected in eight of ten water utilities surveyed by the Environmental Protection Agency (4) as well as in other drinking water sources.

Metabolism

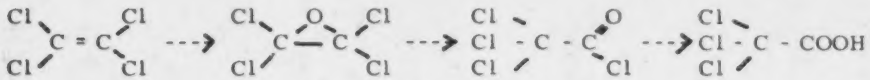
Tetrachloroethylene usually enters the body through the lungs although absorption is also possible through the skin or gastrointestinal tract. Regardless of the absorptive site, virtually all is excreted unchanged through the lungs. Daniel (3) administered ^{36}Cl-labeled tetrachloroethylene by stomach tube to rats and recovered 98 percent of the radioactivity in the expired air within 48 hours. After exposure to tetrachloroethylene, human subjects excrete most of the absorbed compound through the lungs within 24 hours. Following repeated exposures, a prolonged exponential decay of the compound in the subjects' breath was observed extending for 14 days or more (14). An epoxide, which has been recovered as an intermediate, is the first metabolic product. This

Table 10. Distribution of tetrachloroethylene.*

Irradiated beef µg/kg		Thermally sterilized beef µg/kg		Frozen beef control µg/kg		Raw beef µg/kg	Atmosphere µg/m³	Water µg/l	Food µg/kg	Miscellaneous µg/kg
Cooked	Uncooked	Cooked	Uncooked	Cooked	Uncooked					
9	8	9	11	10	12	4	Sea stations - 0.005 Rural Northwest - 0.15 Western Ireland - 0.2 Los Angeles - .07-31 New Jersey - <0.1-72 Submarine - 814 Simulated spacecraft - 14	Atlantic - 0.005 Liverpool Bay 0.12 (ave) 2.6 (max) Municipal water Miami Ottumwa Philadelphia Cincinnati N.Y.C. 0.07 - 0.46 Tucson Lawrence Grand Forks Connecticut-Trace -220 Italian wells (combined tri- and tetrachloro-ethylene) Suburban - 4-38 City - 38-450 Provincial - 39-348	Dairy products-milk - 0.3 Cheese (cheshire) - 2. Butter - 13 Meat - Beef steak - 0.9 Beef fat - 1.0 Pig liver - 5. Oils and fats - Margarine - 7. Olive oil - 7. Vegetable oil - 0.01 Castor oil - 3. Beverages Fruit juices (canned) - 2 Instant coffee - 3. Tea (packet) - 3. Fruits and vegetables Potatoes - 0.7 Apples - 2. Pear - 2. Tomato - 1.2 Bread - 1.	Marine algae - 13-22 Invertebrates - 0.05-15. Fish Fresh - <0.1-11 Liver - 1-41 Birds Muscle - 0.7 Liver - 1.5-3.2 Eggs - 1.3 - 39. Kidney - 6.4 Seal Blubber - 0.6-19 Liver - 0-3.2 Human tissue Fat - 0.1-29.2 Kidney - 0.5-6 Liver - <0.5-4.3 Brain - <0.5 Effluents from textile mills

*See Table 5, footnote a.

undergoes a slow rearrangement to trichloroacetyl chloride, which is then rapidly hydrolyzed to yield trichloroacetic acid as the major end product (16).



Only traces of trichloroethanol were excreted in the urine of mice, rats or man after exposure to tetrachloroethylene vapor (6).

Toxicity

Tetrachloroethylene is relatively nontoxic after acute exposure. This is evident from the LD_{50} values shown in Table 20, as well as by the TLV for workroom exposure (100 ppm or 535 mg per m^3) (1). Men exposed to 1000 ppm showed slight inebriation in 45 minutes but no narcosis after 95 minutes. At levels of 2000 ppm, light narcosis was produced within a few minutes (2). Stewart et al. (14) exposed human volunteers to 100 ppm for 7 hours daily for 5 consecutive days. Over half complained of mild eye, nose or throat irritation developing within the first few hours and then usually subsiding. About one-quarter reported mild headaches. Neurological, pulmonary and laboratory tests were normal. However, Kylin et al. (9) reported significant fatty degeneration of the liver in mice chronically exposed to atmospheres of 200 ppm for 4 hours daily, 6 days weekly for periods of 1 to 8 weeks.

Table 20. Acute toxicity of tetrachloroethylene.

Animal	Route	LD_{50}	Reference
Mouse	Oral	5.2 ml/kg	15
	Intraperitoneal	4.6 g/kg	7
	Intraperitoneal	5.7 g/kg	5
Rat	Inhalation	>3000 ppm (8 hr)	12
	Inhalation	>9000 ppm (3 hr)	2
Dog	Intraperitoneal	3.4 g/kg	8

Pregnant mice and rats were exposed to 300 ppm tetrachloroethylene for 7 hours daily on days 6 to 15 of gestation (15). Cesarean sections were performed on gestation days 21 in rats and 18 in mice. The tetrachloroethylene exposure to the pregnant mice and rats caused no significant maternal embryonal or fetal toxicity nor any teratogenicity.

An unpublished study (11) recently completed for the National Cancer Institute revealed a significantly increased incidence of hepatocellular carcinoma in both male and female B6C3F1 mice receiving large doses of tetrachloroethylene. The compound dissolved in corn oil was administered by gavage five days per week for 78 weeks followed by an observation period of 12 weeks. The time-weighted-average dosages for male mice were 1072 and 536 mg per kg per day; and for female mice were 772 and 386 mg per kg per day.

Both treated and control mice displayed various neoplastic and other lesions. However, primary malignant tumors of the liver were significantly higher in the mice receiving tetrachloroethylene (Table 21).

Table 21. Incidence of hepatocellular carcinoma in mice receiving tetrachloroethylene.

Treatment	Males	Females
Controls	7/79	0/20
Low dose	32/49 (P <0.001)	19/48 (P <0.001)
High dose	27/48 (P <0.001)	19/48 (P <0.001)

The time to the first observed tumor was 27 weeks for male mice and 41 weeks for the females.

Male and female rats were also exposed to two dose levels of tetrachloroethylene administered as described above: 941 and 471 mg per kg per day for male rats and 962 and 481 mg per kg per day for female rats. There was no observable carcinogenic effect of the compound in rats but the results were considered inconclusive because of the poor survival of the animals. Half of the high dose males and females died within 44 and 66 weeks, respectively. Lesions indicative of pneumonia were observed in most control and dosed aminals alike at necropsy. A high incidence of the tetrachloroethylene-treated rats displayed toxic nephropathy.

Discussion

It has been convincingly demonstrated that the small amounts of tetrachloroethylene detected in irradiated beef were of extraneous rather than radiolytic origin. Thus, there is no significant difference in concentration between the irradiated and nonirradiated beef. In some samples of beef supplied by the same processing firm, no tetrachloroethylene could be detected. In the numerous publications on irradiated beef and other meats, the presence of tetrachloroethylene has never been reported. Similarly, Merritt and co-workers (10), with many years' experience with beef irradiation, state they have rarely detected chlorinated hydrocarbons, and in these rare cases, the amount detected was independent of the radiation dosage. To verify the nonradiolytic origin of the tetrachloroethylene in beef, two separate samples of beef were exposed to increasing doses of gamma irradiation. The levels in the nonirradiated samples were zero and 6 μg per kg respectively. After exposure of each sample to 30, 60, 90 and 120 kGy (3, 6, 9, 12 megarads) the tetrachloroethylene concentrations were unchanged, remaining at 0 in the one sample and 6 μg per kg in the other.

Nevertheless, the recent indictment of tetrachloroethylene as a carcinogen --- even at levels a million times greater than its intake from beef --- intensified a search for the source of contamination. It was discovered that tetrachloroethylene was used as a cleaning solvent in the meat packing plant and stored near the beef processing area. To trap the compound, samples of lard, free from tetrachloroethylene, were placed at various sites. In one of the beef-processing areas the lard was found to contain 91 ppb of tetrachloroethylene, indicating a significant atmospheric contamination at this site.

The Committee concludes that the small amount of tetrachloroethylene detected in each type of beef sample represents a contaminant from prior stages of preparation, unrelated to the irradiation process. The exercise of reasonable care during all processing stages should eliminate this compound from beef.

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VII. GENERAL DISCUSSION

As pointed out earlier, this report reviews only those compounds which were detected in beef irradiated and analysed by the techniques employed at the Natick Laboratories and described in the experimental section (see pages 10 - 15). Major modifications of these irradiation, isolation or analytical procedures could change the nature or amount of the compounds identified. In attempting to assess the possible health hazards of these compounds, the Committee was often frustrated by the paucity of information on their toxicity. Such gaps in our knowledge have been pointed out in the individual sections and additional studies in these areas are highly desirable.

By conventional toxicological standards, the concentration of each compound was low, as was the total of all the compounds. For those compounds where such data are available, the least toxic doses are several orders of magnitude greater than the contribution from irradiated beef. There seems no chance that the volatile compounds in the irradiated meat could cause an acute intoxication following its consumption.

Evaluation of possible chronic toxicity is a more difficult and uncertain task. Virtually every compound under consideration has been found in significant amounts in commonly consumed natural and processed foods. Very few of these products have been subjected to the long-term animal studies or to the rigorous epidemiological surveys that would detect subtle or slowly developing pathology or carcinogenesis. The Committee gave this problem particular attention and examined closely all data related to chronic toxicity or carcinogenicity.

Several alkanes and alkenes and one aromatic hydrocarbon (benzene) produced by beef irradiation have been implicated as carcinogens or co-carcinogens under certain conditions.

Several higher alkanes promoted tumor production when painted on mouse skin pretreated with carcinogenic doses of polycyclic aromatic hydrocarbons. These results were considered to have little relevance to the effect of alkanes in irradiated beef. Not only were the routes of administration quite different, but the doses required in these experiments were huge compared with the amounts consumed in beef.

Relatively little is known of the fate and action in the body of the various alkenes found in irradiated beef. It is now generally accepted that epoxides are obligatory intermediates in their metabolism and epoxides are viewed by many investigators as potential carcinogens. This view is

supported by the findings that such potent carcinogens as benzo(a) pyrene, aflatoxin and vinyl chloride seem to owe their carcinogenicity to their conversion to epoxide intermediates. On the other hand, many epoxides or compounds having epoxide metabolic intermediates are considered to be noncarcinogenic. Of all the epoxide metabolic intermediates likely to be formed from the alkenes in irradiated beef, very few have been tested for tumorigenicity. Of these, only epoxyhexadecane has caused increased tumor production and these results are equivocal. It appears that there may be structural features which cause some epoxides to be carcinogenic while others are not. It is not possible at this time to designate the specific structural or electron distribution characteristics that impart carcinogenicity to an epoxide intermediate. Additional studies are desirable, but available evidence does not implicate the alkenes in irradiated beef as carcinogens when ingested in the amounts present in these samples.

Animal studies have failed to demonstrate a leukemogenic action of benzene and more definitive studies are necessary. The amount of benzene ingested from irradiated beef is less than 2 μg per day, an extremely small fraction of that absorbed from such unavoidable sources as the atmosphere, municipal water supplies and numerous foods. The amount consumed from the irradiated beef is believed to add an insignificant increment to the usual body burden.

The Committee considered, too, the possibility that interactions in the body among the various volatile compounds in irradiated beef might cause toxicity. The possibility of additive or synergistic effects cannot be excluded. There are, however, no known or suspected dangerous interactions among these compounds and the lack of data renders unprofitable any further speculation along these lines at the present time.

VIII. CONCLUSION

The Committee has examined the available evidence on the possible health effects of the various volatile compounds identified in beef prepared by low-temperature irradiation preservation. In its opinion, the data do not demonstrate or suggest that the volatile compounds present any significant increment of hazard to the public from the normal consumption of beef processed in this way.

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AD_____

EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

SUPPLEMENT I
FURTHER TOXICOLOGICAL CONSIDERATIONS
OF VOLATILE COMPOUNDS

March 1979

Prepared for

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
DEPARTMENT OF THE ARMY
FORT DETRICK, FREDERICK, MD 21701

under

Contract Number DAMD-17-76-C-6015

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alkynes	hexane	

20. ABSTRACT (Continue on reverse side if necessary and identify by block number)

The recent literature is reviewed of the volatile compounds identified in irradiated beef. Of particular interest were the regulatory actions initiated by the Occupational Safety and Health Administration reducing the maximum acceptable concentration of benzene in the workplace atmosphere from 10 to 1 parts per million, because of the suspected leukemogenic action of the compound. This action is being contested in the courts. Hexane and toluene have been shown to produce neurologic symptoms when inhaled in high

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concentrations to achieve a state of euphoria. Some evidence suggests that methyl ethyl ketone (2-butanone) may have similar effects in inhalant abusers. Each of these compounds is found in irradiated beef but at levels several orders of magnitude less than those producing these toxic effects. The authors conclude that there is no evidence that consumption of reasonable quantities of beef irradiated in the described manner would constitute a hazard to health.

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EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

SUPPLEMENT I

FURTHER TOXICOLOGICAL CONSIDERATIONS OF VOLATILE COMPOUNDS

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SUMMARY

The U.S. Army has developed a process for the preservation of beef by high-dose irradiation in vacuo at about -30°C. A total of 65 volatile compounds in concentrations of 1 to 700 μg per kg was identified in the irradiated beef. A number of these were also found in equal or greater concentrations in nonirradiated beef samples. Most of the radiolytic products were saturated and unsaturated aliphatic hydrocarbons, containing 2 to 17 carbon atoms. There were, in addition, several alcohol, aldehyde, and ketone derivatives, the aromatic hydrocarbons benzene and toluene, and two sulfur-containing compounds. In 1977, the Select Committee on Health Aspects of Irradiated Beef reviewed critically the available data on each of these compounds and concluded that the evidence indicated no grounds to suspect them of constituting a hazard to health to persons consuming reasonable quantities of beef irradiated in the described manner.

Since this 1977 report by the Select Committee, additional publications have appeared on the biological effects of some of these compounds. In addition several government agencies are scrutinizing the possible toxic effects of benzene and toluene because of their ready availability to the public and the exposure of industrial workers to their vapors. For these reasons, it was deemed desirable to review once again any possible hazard of known radiolytic products from beef in the light of newly available data.

Upon careful review of recent studies, the Select Committee found little relevant, supplementary information on the compounds under consideration. Several reports attest to the neurotoxicity of hexane and toluene when these solvents are inhaled repeatedly and intentionally to induce euphoria. More stringent standards have been imposed for permissible levels of benzene in the workplace, but these are now being contested in the courts. New data suggest that methyl ethyl ketone may accentuate neuropathies induced by hexane or methyl n-butyl ketone. The exposure levels of these substances in the environment or upon voluntary inhalation are far higher than are possible from irradiated beef or from various natural food sources in which these compounds are also found. Few recent reports were concerned with the other volatile compounds found in irradiated beef.

Since the reported toxicities of the above compounds occur only at exposures several orders of magnitude greater than found in irradiated beef, the Select Committee reaffirms its original conclusion that the volatile radiolytic compounds appear to pose little or no health hazard when reasonable quantities of beef irradiated in the described manner are consumed.

FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB) provides scientific assessments of topics in the biomedical sciences. Reports are based upon comprehensive literature reviews and opinions of knowledgeable investigators who are actively working in specific areas of biology and medicine.

A technical report entitled "Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef" (AD-A045716) was published in August, 1977 by an ad hoc Select Committee with the assistance of the LSRO staff. It reviewed the biological effects of 65 volatile compounds found in irradiated beef. The present report supplements this earlier review with material which has subsequently come to the attention of the Committee.

The Select Committee accepts the responsibility for the contents of this report. Special appreciation is expressed to Dr. Walter M. Urbain, Special Consultant, for his helpful comments in the preparation of this report. The report was approved by the Select Committee, the Director of LSRO, and by the LSRO Advisory Committee composed of representatives of each constituent society of FASEB, under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures, the report was approved and transmitted to the U.S. Army Medical Research and Development Command by the Executive Director, FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of the individual members of its constituent societies.

Kenneth D. Fisher, Ph.D.
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I. INTRODUCTION

As part of a continuing study on the wholesomeness of irradiated meats, the Food Sciences Laboratory of the U.S. Natick Research and Development Command has determined the volatile compounds produced when beef is treated at about -30°C with 56 kGy (5.6 Mrads) of gamma ray or high energy electron radiation. Sixty-five compounds were identified after irradiation with concentrations ranging from 1 to 700 μg per kg beef (parts per billion). Some of these compounds were of radiolytic origin while others were present in equal or greater amounts in nonirradiated samples. The health aspects of each of these compounds, whether radiolytic or nonradiolytic, were reviewed by a Select Committee assembled by the Life Sciences Research Office (1977). This report is intended to supplement the earlier review by consideration of recent publications and additional information which have subsequently come to the attention of the Committee. A complete listing of all compounds and their concentrations is given in the original report.

II. COMPOUNDS DETECTED*

A. HYDROCARBONS

1. Alkanes (pp. 37-46)
2. Alkenes and alkynes (pp. 47-55)

The entire series of normal alkanes and alkenes from C-2 to C-17 were found in irradiated beef. The concentrations ranged from 164 to 696 µg per kg for alkanes and from 28 to 618 µg per kg for alkenes. Small amounts (19 to 45 µg per kg) of the 2-methyl isomers of propane, propene, butane, pentane, and heptane were also present. In addition, two alkynes (decyne and undecyne: 23 and 4 µg per kg) and four dienes (tetra-, penta-, hexa-, and heptadecadiene: 16 to 706 µg per kg) were identified.

Of these aliphatic hydrocarbons, hexane (209 µg per kg irradiated beef) has been the most thoroughly investigated. It is used as a solvent in glues, varnishes, cements, inks, and a number of other products (National Institute for Occupational Safety and Health, 1977). Significant and repeated exposures to this compound are largely confined to two groups of individuals: the industrial worker and the abuser of inhalants. The former group is exposed because of workroom contamination while individuals in the latter group deliberately expose themselves to achieve a state of euphoria or "high".

The acute toxicities of the volatile alkanes are relatively low, allowable concentrations in workplace atmospheres range from 100 parts per million (ppm; 360 mg per m^3) for hexane to several thousand ppm (>2000 mg per m^3) for the simplest homologues: methane, ethane, propane (American Conference of Governmental Industrial Hygienists, 1976). However, numerous reports attest to the toxicity for man (Oishi et al., 1964, Yamamura, 1969; Herskowitz et al., 1971) and animals (Miyagaki, 1967; Ishii et al., 1972 Schaumburg and Spencer, 1976) of chronic exposure to hexane or hexane-containing solvents. Yamamura (1969) conducted a comprehensive clinical study and reported nerve damage in 93 of 1662 workers who were exposed to hexane in an industrial setting. He estimated that the affected individuals had been exposed to concentrations of 500 to 2500 ppm (1.8 to 9.0 g per m^3 of hexane for 8 hours or more daily, 6 or 7 days weekly for several months or more. Similarly, Yamada (1967) described 17 cases of polyneuropathy among workers in small laminating plants with atmospheric hexane concentrations of 1000 to 2500 ppm and in pharmaceutical plants with 500 to 1000 ppm. Symptoms of intoxication appeared within 1 to 2 months after initial exposure. Herskowitz et al. (1971) reported three cases of polyneuropathy among factory

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*Page citations refer to the original report (LSRO, 1977) which should be consulted for additional details.

workers exposed to an average of 650 ppm hexane for 2 to 4 months. The observed human neuropathies involved both the sensory and motor systems, with characteristic manifestations of muscular weakness or atrophy, hypesthesia, and hypoactive reflexes.

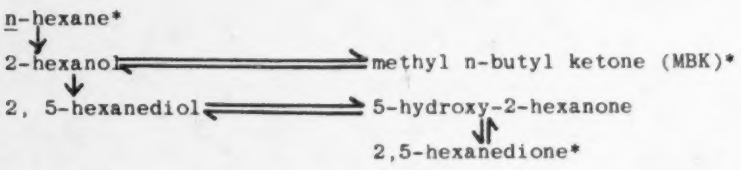
More recent studies including both industrial exposure (Paulson and Waylonis, 1976) and solvent abuse (Gonzalez and Downey, 1972 Goto et al., 1974, Towfighi et al., 1976) have confirmed these earlier findings. Although other volatile compounds were present in the inhaled solvents, hexane appeared to be the major contributor to the observed toxicity. Some of the inhalant-abuse patients had inhaled hexane-free volatiles for years without apparent detrimental effect, but had developed crippling peripheral neuropathy within a matter of months after switching to products containing hexane (Bruckner and Peterson, 1977).

Experimental demonstration of the neurotoxicity of hexane was provided by Schaumburg and Spencer (1976) who observed degenerative neurological changes in adult Sprague-Dawley rats inhaling highly purified hexane (400 to 600 ppm) continuously for 162 days or receiving 550 to 2000 mg per kg of the compound subcutaneously 5 days weekly for 18 to 35 weeks. Degeneration in the central and peripheral nervous systems was noted in both groups of animals within 2 to 3 months. Widespread axonal degeneration in the central nervous system was regularly observed and was similar to that reported in nerve biopsies from patients inhaling glue vapors containing hexane (Goto et al., 1974, Korobkin et al., 1975).

The most apparent effects of hexane poisoning are upon the nervous system; evidence of damage to other tissues is scanty. Paulson and Waylonis (1976) observed elevated serum levels of lactic dehydrogenase and glutamic oxaloacetic transaminase which suggested liver damage in one patient with hexane-induced neuropathy. Nix et al. (1977) reported liver damage in mice exposed to high atmospheric concentrations (6000 to 12000 ppm) of mixed hexanes for 2 to 49 days. Hepatic lipid accumulation was noted in rats (Bohlen et al., 1973) and in guinea pigs (DiVincenzo and Krasavage, 1974) after hexane inhalation. No reports have been found of toxicity induced by hexane concentrations below the maximum allowable concentration in workroom atmospheres (100 ppm).

It now appears that a metabolic product, 2,5-hexanedione rather than hexane itself, is the active neurotoxic agent. Cats given 0.5 percent of this product in drinking water for periods up to 136 days developed widespread axonal degeneration similar to that observed with hexane intoxication (Schaumburg and Spencer, 1978). Methyl n-butyl ketone, also believed to be a hexane metabolite, has produced similar neurologic damage in industrial workers (Allen et al., 1974) and experimental animals (Duckett et al., 1974, DiVincenzo et al., 1978).

The interrelationship of these compounds is suggested in the following scheme (DiVincenzo et al., 1976, Nix et al., 1977):



*demonstrated neurotoxic agents

Hexane and related compounds appear to be metabolized by an inducible microsomal enzyme system. When mice were continuously exposed to an atmosphere containing 2.5 to 3 percent hexane, the monooxygenase capacity of the liver increased dramatically (Krämer et al., 1974). Three isomeric alcohols were formed from hexane by the liver microsomes, with 2-hexanol predominating. Couri et al. (1978) also found 2-hexanol in the urine of guinea pigs after intraperitoneal injection of n-hexane. When the guinea pigs were pretreated with phenobarbital, the urinary 2-hexanol increased.

Staples and Marks (1979) are currently studying the possible teratogenic effects of n-hexane in pregnant CD1 Charles River mice. No results are yet available.

The Committee knows of no study demonstrating a neurotoxic effect of the other alkanes identified in irradiated beef. However, Gaultier et al. (1973) reported polyneuropathy in five workers exposed to a solvent containing 80 percent pentane, 14 percent heptane, and 5 percent hexane. They suggested that pentane or heptane, rather than hexane, might be responsible for the observed neurologic damage. Indirect support for this suggestion comes from the observations of Frommer et al. (1972) who noted that rat liver microsomal preparations hydroxylate other low and medium-length alkanes as well as hexane. Thus, all possible isomeric heptanols were produced when heptane was incubated with microsomal preparations, with 2-heptanol predominating. This reaction is analogous to that found with hexane (Krämer et al., 1974), in which microsomal incubation also hydroxylated all possible positions, with a preponderance of 2-hexanol.

No additional pertinent information has been found for the other aliphatic hydrocarbons of irradiated beef.

3. Aromatic Hydrocarbons (pp. 56-67)

Benzene, toluene, and xylene were detected in small amounts (<0.1 ppm) in the irradiated beef samples. Benzene and toluene increased slightly with increased radiation doses (LSRO, 1977) and are presumed to be radiolytic products. The concentration of xylene, however, was no greater in irradiated than in nonirradiated beef and is of nonradiolytic origin.

Benzene

A voluminous literature exists on the toxicity and metabolism of benzene. The major area of interest has been the effect in man of chronic inhalation of its vapor; this aspect has been reviewed comprehensively in several recent reports (NIOSH, 1974, National Research Council, 1976, Haley 1977, Occupational Safety and Health Administration, 1978). A leukemogenic action has long been suspected because of the occurrence of leukemia among some workers chronically exposed to benzene (NRC, 1976; Aksoy, 1978). Although the affected individuals had also been exposed in most cases to other compounds in the work place, benzene appeared to be the common agent. Early epidemiologic surveys yielded conflicting results. In one major study, an annual incidence of 13 cases of leukemia per 100,000 persons was found among 28,500 shoeworkers exposed to benzene, compared with 6 cases per 100,000 among the general population (Aksoy et al., 1974). However, there was no greater incidence of leukemia among 38,000 petroleum workers potentially exposed to benzene than among unexposed individuals (Thorpe, 1974). Reviewing the available data, the NIOSH (1974) concluded that "the possibility that benzene can induce leukemia cannot be dismissed," but it emphasized the need for additional, careful, epidemiologic studies.

Since this NIOSH review, additional reports have appeared suggesting a relationship between benzene exposure and leukemia (McMichael et al., 1975, 1976, Andjelkovic et al., 1976, Monson and Nakano, 1976, Infante et al., 1977a; Ott et al., 1978). Of especial interest was the survey of workers involved in the production of Pliofilm® (Infante et al. 1977a,b). In this survey the influence of other solvents was largely excluded, for in addition to benzene, the workers were exposed only to hydrochloric acid, soda ash, and small amounts of antioxidants and plasticizers. Workers occupationally exposed to benzene during the years 1940 to 1949 were followed for vital status up to 1975. Of 748 workers exposed during this period, seven died from myelogenous or monocytic leukemia, an incidence seven times that observed in the general population or in workers not exposed to benzene ($P<0.002$). The level of exposure to benzene by the workers during this period (1940-1949) is uncertain. In 1941, the maximum allowable concentration was 100 ppm which was lowered to 50 ppm in 1947 and to 35

ppm in 1948 for an 8-hour time-weighted average (Infante et al., 1977b). Since 1971, the allowable concentration has been 10 ppm. The statistical treatment in this study by Infante et al. (1977a,b) was criticized by Tabershaw and Lamm (1977), but defended by the original investigators (Infante et al., 1977c).

The NIOSH report (1976) concluded that the clinical and epidemiologic evidence demonstrated the leukemogenicity of benzene in man. The report recommended that no worker be exposed to air concentrations in excess of 1 ppm (3.2 mg per m^3) on a time-weighted average. This recommendation was adopted by OSHA (1977), which established emergency temporary standards on May 3, 1977, reducing the permitted employee exposure to benzene from 10 ppm to 1 ppm based on an 8-hour time-weighted average. On February 10, 1978, these levels were adopted as the permanent standard for the regulation of worker exposure to benzene (OSHA, 1978). Industry contested these regulations, arguing that experimental evidence was lacking that benzene at the existing authorized level of 10 ppm was harmful. In October 1978, the Fifth Circuit Court of Appeals in New Orleans ruled against OSHA. The Supreme Court has agreed to review the ruling and a final decision is expected in 1980 (Carter, 1979).

In June, 1977, the Environmental Protection Agency (EPA, 1977) also concluded that the evidence implicating benzene as a leukemogenic agent was sufficiently strong to merit its addition to the list of hazardous air pollutants.

The opinion that benzene is leukemogenic is not accepted by all investigators. Their reluctance to label benzene a carcinogen has rested both upon the poor quality of human epidemiologic data and upon a consistent failure to produce leukemia or cancerous tumors in experimental animals (NRC, 1976, Ward et al., 1975). Pancytopenia has been produced in animals by benzene injection (Kissling and Speck, 1972), but experimentally induced leukemias or carcinomas have not been reported. At a recent seminar, Maltoni claimed that he had produced various tumors in rats by feeding benzene for periods up to 76 weeks (Anonymous, 1977). Of 70 rats fed 250 mg benzene per kg body weight, five developed tumors of the Zymbal gland, five had dermal tumors, and three a "variety of other rare tumors". No leukemias were reported. Of 60 rats fed 50 mg per kg, two had Zymbal gland tumors and one a dermal tumor. None of more than 300 control rats developed tumors of any type. A detailed account of this study has not yet appeared in a scientific journal.

Despite numerous metabolic studies, both *in vitro* and *in vivo*, the mechanism of benzene action on the hematopoietic system remains unclear. Some workers have attributed the toxicity to benzene itself (Ikeda et al., 1972), while others believe a metabolite is responsible (Lee et al., 1974). In an attempt to resolve this controversy, Timbrell and Mitchell (1977) studied the

effects of various microsomal enzyme inducers and inhibitors. If benzene itself were the toxic agent, metabolic inhibitors would be expected to increase, and metabolic inducers to decrease, the toxicity of benzene. The opposite effects would be expected if a metabolite rather than the intact benzene were the toxic agent and the metabolite were not destroyed before reaching the target organ. However, the investigators found that both inhibitors (piperonyl butoxide, cobaltous chloride) and an inducer (phenobarbital) of microsomal cytochrome P-450 tended to reduce the toxicity of subcutaneously administered benzene, suggesting a complex relationship between the metabolism and toxicity. Oral pretreatment with benzene potentiated the toxicity. The most significant effect of such benzene pretreatment was a selective increase in quinol excretion, indicating a possible role of this metabolite or a precursor in benzene toxicity. The mechanism of benzene action remains uncertain and continues to be a source of active investigation.

To retain perspective on the possible hazard of benzene, it is important to keep in mind the relative exposures from various sources. An industrial worker exposed to the contested standard of 1 ppm would obtain approximately 10 mg benzene during an 8-hour day or about 1000 times the amount in 1 pound of irradiated beef. Benzene has been reported in many natural foods including meat, fish, vegetables, nuts, dairy products, eggs, and beverages (Van Duuren, 1977). There is evidence that conventional cooking will produce an increase in benzene, and "large" amounts have been reported in boiled beef and beef broth (Cheng and Peterson, 1977).

Toluene

The cell-selective toxicity of benzene to blood and blood-forming organs has also been attributed to toluene, partly because of structural similarities and partly because crude preparations of toluene produce benzene-like toxicity (Wolf, 1972). Contamination with benzene has hindered early toluene toxicity studies (accordingly benzene-comparable preparations of toluene may contain as much as 25 percent benzene (Cohn, 1975). Studies using purified toluene have failed to demonstrate a myelotoxic effect (Wolfe, 1972; Cox, 1976). In fact, a recent study suggests that toluene may actually exert a protective effect against the hematopoietic toxicity of benzene (Andrews et al., 1977). Toluene (1700 mg/kg) and benzene (300 and 900 mg/kg) were injected subcutaneously in adult, male, Sprague Dawley rats. This treatment reduced markedly the [uptake] of benzene metabolites in urine and bone marrow and reduced also the benzene-induced inhibition of ^{59}Fe uptake by erythrocytes. However, the concentration of benzene in bone marrow was not reduced, thus providing support for those contending that a benzene metabolite(s) is the myelotoxic agent. Toluene has also been shown to inhibit the biotransformation of styrene (Ikeda et al., 1972) and tetrachloroethylene (Ikeda, 1976).

Reports prior to 1973 on the health aspects of toluene were reviewed by NIOSH (1973) and subsequent literature by Hayden et al. (1977) and an EPA committee (1978). The main toxic effect of toluene appears to be upon the central nervous system. Weiss et al. (1978) reported an excitatory effect of toluene in key-pecking behavior of pigeons at an atmospheric concentration of 600 ppm, but a depressant effect at 3200 ppm. Takeuchi and Okonaga (1977) attempted to detect central nervous effects by studying the electroencephalographic changes during spontaneous sleep of rats exposed to various atmospheric levels of toluene for 4 hours. The investigators concluded that 1000 ppm of toluene vapor prevented sleep from entering the slow-wave phase but facilitated its entry into the paradoxical phase. Concentrations of 2000 and 4000 ppm produced sleep disturbances, including myoclonic seizures at both levels.

In healthy, adult men, reaction time was impaired by 20-minute exposure to 300 ppm toluene in inspired air. Exposure to 700 ppm toluene was necessary to produce significant impairment in perceptual speed, measured by the time required to identify identical numbers in 60 separate columns (Gamberale and Hultengren, 1972). Lewis and Patterson (1974) observed various symptoms, including mental confusion, exhilaration, and fatigue when human subjects were exposed for 3 hours at 600 ppm.

Reports are rare of toxic effects by toluene on other organ systems. Bruckner and Peterson (1976) failed to detect any injury to lung, liver, or kidney in mice exposed to 4000 ppm of toluene vapor for 3 hours daily, 5 days per week, for up to 8 weeks. Cardiac arrythmias (Reinhardt et al., 1971) and renal tubular acidosis (Taher et al., 1974) have been associated with toluene "sniffing" but the specific role of toluene was not established definitively. Hayden et al. (1977) in a recent review concluded that there is little firm evidence that toluene exerts a specific toxic effect on any organ system.

The Chemical Industry Institute of Toxicology has instituted an investigation of the possible toxic and carcinogenic effects of toluene following chronic inhalation exposure to a commercial product (containing 100 ppm benzene). Only preliminary results are available (EPA, 1977). Groups of 30 rats each (strain and age not stated) were exposed to 30, 100, 300, or 1000 ppm of the commercial toluene preparation for 90 days. No significant differences from controls were noted in body weight, hematology, blood and urine chemistries, or frequency of histopathologic changes. Alopecia around the ears occurred in some female rats and red deposits or discharges from the nose and eyes were noted in some male rats. The nature of the red discharge was not indicated.

The concentrations of toluene in irradiated beef were 50 to 65 µg per kg, approximatoly the same as in thermally sterilized beef. Toluene has been detected in about 30 foods, with concentrations of 500 µg per kg in refrigerated fish. Average air samples in different cities ranged from 11 to 140 µg per m^3 (LSRO, 1977). Concentrations in single and composite samples of industrial water effluents have been found to range from 40 to 280 µg per l (EPA, 1978).

Xylene

Xylene is found only in trace amounts in beef (4 µg/kg) and is not a radiolytic product.

B. OXYGEN CONTAINING COMPOUNDS

1. Alcohols (pp. 68-72)

The only alcohols detected in irradiated beef were methanol and ethanol. Publications concerning the toxicology of these compounds, especially the latter, continue to appear, adding to an already mammoth bibliography. However, none of the recent publications is relevant to the present discussion or modifies the original report (LSRO, 1977).

2. Aldehydes (pp. 73-79)

The following aldehydes were detected in irradiated beef in concentrations from 10 to 398 µg per kg: 2-methyl pentanal, undecanal, dodecanal, tetradecanal, pentadecanal, hexadecanal, octadecanal, hexadecenal, and octadecenal. No recent study on any of these aldehydes has come to the attention of the Select Committee.

3. Ketones (pp. 80-87)

Only the two simplest ketones, acetone and methyl ethyl ketone (MEK, 2-butanone) were detected in irradiated beef. Both are widely used as industrial solvents and both have low acute toxicities. Browning (1965) cited studies in which workers have been exposed to 1000 to 2000 ppm of acetone for years with no ill-effects other than temporary headaches or anorexia. Similarly, the effects of MEK exposure are generally reported to be mild and temporary (Elkins, 1959). However, Viader et al. (1975) reported a case of neuropathy in a worker exposed for 2 years to a tetrahydrofuran-based glue containing MEK as the solvent.

Couri and coworkers (1977) have studied the influence of inhaled vapors of several ketones on young Wistar rats. Rats were exposed to 750 ppm of MEK, 225 ppm of methyl n-butyl ketone (MBK, 2-hexanone), or a mixture of MEK/MBK. Hexobarbital sleeptimes were significantly reduced following exposure to MEK or to the mixture of MEK with MBK, but not to MBK alone. Hepatic microsomal activities of various enzymes (aniline hydroxylase, aminopyrine demethylase, neoprontosil reductase, p-nitrobenzoate reductase) increased two- to three-fold in the MEK and MEK/MBK exposure groups compared with controls.

Exposure to MBK causes peripheral neuropathy similar to that already described for hexane (p. 2). Both hexane and MBK have a common metabolite, 2, 5-hexanedione, and this is believed to be the toxic principle (Couri et al., 1978). Cats, rats, and chickens chronically exposed to MBK vapors developed neuropathic signs, while those exposed to MEK did not (Prockop and Couri, 1977). However, a more rapid and severe toxicity was observed with combined vapors of MEK/MBK than with MBK alone. Two of six rats exposed to vapors of MBK (400 ppm) exhibited mild neuropathy, but no fatalities, during 60 days of continuous exposure. In the MEK/MBK (750/225 ppm) group, the experiment was limited to 23 days because of the severity of the neuropathy, with all six rats dying during exposure, or within 2 weeks after removal from the exposure chamber (Abdel-Rahman et al., 1976).

The recent report of Altenkirch et al. (1977) suggests that MEK in high concentrations may have neurotoxic effects. These investigators described a sudden outbreak of polyneuropathy among 18 young people sniffing a glue thinner containing hexane and MEK. These individuals had sniffed the same brand of thinner, containing 31 percent hexane, 30 percent toluene, 28 percent ethyl acetate, and 11 percent of other hydrocarbons, for up to 7 years, without apparent ill-effects. There had been no reported adverse effects among an estimated 2000 adolescents who had sniffed this product for various periods of time. In the early summer of 1975, the formulation of the thinner was changed to contain 11 percent MEK and 16 percent hexane. The other constituents remained approximately the same. The new thinner caused neurological symptoms in the 18 victims almost identical with those reported elsewhere with hexane. No further cases have been observed since the original formulation was restored in January, 1976.

C. SULFUR-CONTAINING COMPOUNDS (pp. 88-94)

Four sulfides (carbonyl sulfide, dimethyl sulfide, dimethyl disulfide, and hydrogen sulfide) and one thiol (ethane thiol) were detected in irradiated beef at concentrations of 2 to 10 µg per kg (2 to 10 parts per billion). Each of these compounds has been found in commonly consumed foods at levels two to five orders of magnitude greater than these amounts (LSRO, 1977) and

only ethyl mercaptan and dimethyl sulfide showed any increased concentrations after irradiation (10 g/kg). No recent publications on the biological effects of these substances could be found.

D. NITROGEN-CONTAINING COMPOUNDS (pp. 95-98)

Acetonitrile was the only volatile nitrogen-containing compound detected in irradiated beef. The concentration was extremely low (1 to 3 g per kg) and less than that found in frozen controls or thermally sterilized beef, indicating a nonradiolytic origin.

E. HALOGEN-CONTAINING COMPOUNDS (pp. 99-105)

Tetrachloroethylene (perchloroethylene) was the only halogen-containing compound detected in irradiated beef. It was found in some, but not all samples of irradiated beef, and in some nonirradiated samples as well. The compound was shown to be of extraneous rather than of radiolytic origin.

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III. DISCUSSION (pp. 107-108)

Recent reports emphasize the potential risk to industrial workers and solvent abusers chronically exposed to appreciable levels of several readily available volatile compounds. The reported toxicity in virtually all these experimental and clinical studies has resulted from inhalation of 10 to 1000 ppm or more of these compounds for extended periods of time. The quantities inhaled from these exposures are several orders of magnitude greater than would be ingested from the consumption of even large amounts of irradiated beef. Each of the radiolytic compounds discussed in this report are found naturally in various commonly consumed foods.

IV. CONCLUSION (p. 109)

The Committee reaffirms its original conclusion that there is no evidence to suggest that the volatile radiolytic compounds found in beef irradiated in the described manner would constitute a hazard to health of the consumer.

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Air Irradiation

EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

SUPPLEMENT 3
POSSIBLE RADIOLYTIC COMPOUNDS

March 1979

Prepared for

U.S. ARMY MEDICAL RESEARCH AND DEVELOPMENT COMMAND
DEPARTMENT OF THE ARMY
FORT DETRICK, FREDERICK, MD 21701

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Volatile products of beef irradiated with 56 kGy (5.6 Mrad) and approximately -30°C have been identified and their health aspects discussed in a previous report. In addition to these volatile radiolytic compounds, other, nonvolatile products are possible. This report attempts to identify the compounds which might result from beef irradiation; to estimate roughly the concentrations of such products; and to evaluate their possible hazard to health.

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In the absence of direct data, the Committee has utilized findings with model systems and has extrapolated these results to irradiated beef. The uncertainties implicit in such extrapolations are discussed. Rough estimates of beef radiolytic products have been attempted which have permitted speculation of possible toxic effects.

There is very little carbohydrate in beef and its radiolytic products should be relatively innocuous in the amounts produced. Few radiolytic products have been identified from the protein component of beef. The bulk of radiolytic products found in beef has come from the fat molety. Simple triglycerides have been studied extensively and sites of bond scission have been identified. The major products are fatty acids, diglycerides, and diol diesters. The concentrations of these classes have been estimated at approximately 0.5 to 1.0 g per kg irradiated beef. Lesser amounts of many other compounds are possible, including hydrocarbons of varying chain lengths, glycerol, monoglycerides, aldehydes, and ketones. The biological effects of each of these classes have been considered. No evidence is available which indicates a toxicity of any of these compounds at the concentrations anticipated in irradiated beef, although in some cases, inadequate information is available to permit a firm judgment at this time on their possible health effects.

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EVALUATION OF THE HEALTH ASPECTS OF CERTAIN COMPOUNDS FOUND IN IRRADIATED BEEF

SUPPLEMENT II

POSSIBLE RADIOLYTIC COMPOUNDS

March, 1979

Prepared for

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SUMMARY

A number of radiolytic compounds are produced when beef is exposed to sterilizing doses of gamma ray or high energy electron radiation. The identity and concentration of 65 volatile compounds have been determined and their health aspects considered in a previous report. The present report is an attempt to extend these considerations to other possible radiolytic products. In the absence of specific data from irradiated beef, the Committee has utilized the results from model systems of carbohydrates, fats, and proteins to identify possible nonvolatile compounds. Despite the obvious hazard of extrapolating from such simple models to a substance as complex as beef, this method should allow rough estimations of the more likely products.

Simple aliphatic acids and carbonyl-containing compounds may be produced by carbohydrate irradiation, but the small amount of carbohydrate present in beef suggests that the concentrations of such products are low in the irradiated samples. While irradiation of protein is known to produce certain changes few simple compounds attributable to the protein moiety of beef have been detected, although their presence cannot be excluded. Most of the radiolytic compounds thus far detected appear to come from beef fat. Synthetic triglycerides are vulnerable to bond scission at several sites, suggesting a variety of possible radiolytic compounds from the fatty fraction of beef. Rough estimates of the possible concentrations of some of these products in irradiated beef have been attempted by extrapolating data obtained from model lipid systems. The most abundant products appear to be fatty acids, diol diesters, and diglycerides, with significantly lesser amounts of a number of other compounds. The toxicology of these products has been reviewed, wherever possible, but relevant data are lacking or sparse for some of these compounds.

The Committee concludes that many of the radiolytic products in the concentrations estimated to be present, should pose no hazard to consumers of beef irradiated in the described manner. Such products include the individual fatty acids and their simple esters, glycerol, mono- and diglycerides, aldehydes, and aliphatic hydrocarbons. Insufficient data are available to allow judgment of the effects on health of the individual diol diesters and alkylcyclobutanones presumably present. Metabolic and toxicological studies of these compounds are desirable. No evaluation can be made of the other compounds theoretically possible in small amounts, but which have not been demonstrated in irradiated beef or model systems. Because no analysis, however exhaustive, can exclude the possibility of the presence of undetected constituents, no unequivocal demonstration of safety seems possible from consideration of the individual radiolytic products alone. Such analyses, though useful, should be coupled with appropriate animal feeding studies to provide complementary approaches to assure the wholesomeness and safety of irradiated foods.

FOREWORD

The Life Sciences Research Office (LSRO), Federation of American Societies for Experimental Biology (FASEB) provides scientific assessments of topics in the biomedical sciences. Reports are based upon comprehensive literature reviews and opinions of knowledgeable investigators who are actively engaged in work in specific areas of biology and medicine.

A technical report entitled "Evaluation of the Health Aspects of Certain Compounds Found in Irradiated Beef" (LSRO, 1977) was published in August, 1977 by an ad hoc Select Committee with the assistance of the LSRO staff. It reviewed the biological effects of 65 volatile compounds found in irradiated beef. An analysis of the relevant literature on these compounds appearing since this report is included in Supplement I.

Consideration of the radiation chemistry of the major food components suggests that a number of additional compounds could be produced from the exposure of beef to sterilizing doses of ionizing radiation. Most of the compounds discussed in this second supplemental report have not been identified in beef irradiated in the described manner, nor have their concentrations in the beef been determined. Nevertheless, it is believed important to attempt an evaluation of the health aspects of those substances possibly produced during irradiation.

The Select Committee accepts the responsibility for the contents of this report. Appreciation is expressed to Dr. Walter M. Urbain, Special Consultant, for his helpful comments in its preparation. The report was approved by the Select Committee, the Director of LSRO, and the LSRO Advisory Committee composed of representatives of each constituent society of FASEB, under authority delegated by the Executive Committee of the Federation Board. Upon completion of these review procedures, the report was approved and transmitted to the U.S. Army Medical Research and Development Command by the Executive Director, FASEB.

While this is a report of the Federation of American Societies for Experimental Biology, it does not necessarily reflect the opinion of the individual members of its constituent Societies.

Kenneth D. Fisher, Ph.D.
Director
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I. INTRODUCTION

For almost two decades, investigators at the Food Sciences Laboratory of the U.S. Army Natick Research and Development Command have been studying the radiolytic products of meats exposed to sterilizing doses of ionizing radiation (Merritt, 1972; Merritt et al., 1959; 1978). Sixty-five compounds have been identified in beef exposed to an average dose of 56 kGy (5.6 Mrads) of gamma ray or electron irradiation at about -30°C. The concentrations ranged from 1 to approximately 700 µg per kg (parts per billion) of irradiated beef. The health aspects of each of these substances were reviewed by a Select Committee of the Life Sciences Research Office of the Federation of American Societies for Experimental Biology (LSRO, 1977, 1979). The Committee concluded that there were no grounds to suspect that these radiolytic products would constitute a health hazard to persons consuming beef irradiated in the described manner.

The 65 compounds identified and discussed in the original reports probably represent only a small portion of those produced by the irradiation of beef. It was their relative volatility which rendered them especially amenable to gas chromatographic and mass spectrometric analysis. However, many other less volatile products are also possible theoretically from the irradiation of a substance as complex as beef.

The major constituents of beef are water, protein, and fat while inorganic salts, carbohydrates, free amino acids, phosphocreatine, and other soluble organic compounds are present in small amounts. Because of the complexity and variability of natural foods, simple compounds of known structure have usually been the substrates for radiolytic studies. Caution must be exercised in extrapolating results with these compounds to more complex substances. Nevertheless such models are useful in illustrating general processes and in providing a basis for speculation about the radiolytic products of various foodstuffs, such as beef.

II. RADIOLYTIC PRODUCTS OF CARBOHYDRATES

A vast literature is available on the radiation chemistry of carbohydrates. A recent review (Dauphin and St. Lebe, 1977) lists almost 400 references on this subject. Depending on the specific carbohydrate irradiated and the conditions of irradiation, hydrogen, carbon dioxide, aldehydes, ketones, acids, and other compounds are formed. Beef contains only about 0.5 percent carbohydrate in the form of muscle glycogen (Swenson, 1977). No report could be found dealing specifically with the radiolysis of glycogen. However, one would expect its radiolytic products to be similar to those of starch or other polysaccharides. Irradiation of polysaccharides leads to their depolymerization and fragmentation into simpler molecules. When wheat starch was irradiated, glucose, maltose, maltotriose, maltotetrose, and maltopentose were all detected in significant amounts, with the di- and trisaccharides predominating (Ananthaswamy, et al., 1970). Small amounts of simpler compounds were also detected after irradiation of wheat starch, mainly formic acid, formaldehyde, acetaldehyde, and glycolaldehyde. However, glycolysis occurs rapidly following death of the animal, so that most of the glycogen originally present in the beef is converted to lactic acid. Radiolysis of lactic acid gives rise to simple one- and two-carbon compounds.

Degradation of any remaining glycogen would also be minimized by the irradiation of beef in vacuo and at low temperatures, both conditions favoring marked reduction of radiolytic activity. Furthermore, many substances, including amino acids and proteins protect carbohydrates against breakdown by radiolysis (Diehl et al., 1978; Phillips, 1972).

III. RADIOLYTIC PRODUCTS OF PROTEINS

Irradiation produces changes in both the physical and chemical characteristics of proteins, but the changes are not great at doses used in food irradiation. The nature and extent of change depend upon various factors, including the physical structure of the protein, its chemical composition, its native or denatured state, its form during irradiation (dry, wet, frozen), and the presence of other substances. Hydrogen bonds may be disrupted allowing the molecule to unfold; the molecule may undergo dissociation, aggregation, or fragmentation; and individual amino acids may be destroyed. The resulting products are diverse, complex, and difficult to identify or quantify (Urbain, 1977; 1978).

At the amino acid level, the principal radiolytic reactions in oxygen-free solutions are reductive deamination and decarboxylation. These reactions result in the formation of the corresponding organic acids and of amines with one less carbon atom than the original amino acids. Thus, glycine would give rise to methylamine and acetic acid; alanine to ethylamine and propionic acid; etc. In beef, traces of such amines and acids might result from the small amounts of free amino acids present. However, the low irradiation temperature would markedly reduce their production. Taub et al. (1978) have shown that freezing reduced the electron-induced ammonia formation from glycine by approximately 90 percent compared with irradiation in the liquid state. In peptides and proteins, only the terminal and diamino- and dicarboxylic amino acids would undergo deamination or decarboxylation. Irradiation in the frozen state would also sharply reduce other radiolytic effects on the protein molecule. This has been demonstrated dramatically with the enzyme pepsin, which retained approximately 95 percent of its original activity when irradiated at temperatures of -30° to -190°C, but only 10 percent when irradiated at room temperature (Bellamy and Lawton, 1954). No amino acid destruction could be detected when beef was irradiated 60 kGy (6.0 Mrad) at -196°C. The individual amino acid content of the beef after irradiation did not differ measurably from the nonirradiated sample (Kauffman and Harlan, 1969), although the analytical methods employed may have been insufficiently sensitive to detect small changes.

The limited data available suggest that only small amounts of simple radiolytic products from protein would result from beef irradiated at low temperatures in the absence of oxygen. Further information on the nature and quantity of such products is desirable.

IV. RADIOLYTIC PRODUCTS OF LIPIDS

The radiolytic products of beef lipids have been studied more thoroughly than those of proteins or carbohydrates. This emphasis does not imply that the radiolysis of lipids is necessarily of greater significance than that of the other beef components, but rather that it has proved more amenable to available analytical techniques. Also, as implied earlier, there has been limited interest in carbohydrate radiolysis because of the small glycogen content of beef. The structural similarity of the triglycerides and their relatively low molecular weights provide attractive models for bond cleavage studies. Studies can be performed on simple synthetic models which are believed to mimic closely the effects of irradiation on more complex natural fats. Many of the products of irradiation are readily identifiable, which allows the investigators to localize the sites of radiolysis and to predict the structure of additional products not yet detected. For these reasons, the radiolytic products of beef lipids are considered here in greater detail than those of carbohydrates and proteins.

Upon exposure to high energy irradiation, lipid molecules are cleaved at a number of sites to produce free radicals, which may then gain or lose hydrogen, or recombine to form a number of new compounds (Nawar, 1977). The most penetrating studies into the mechanism of lipid radiolysis have been those of Nawar and his colleagues, who have utilized a series of simple triglyceride models containing C_4 to C_{18} fatty acids. From these studies, Nawar (1972; 1977) identified five locations (a-e) in the vicinity of each of the carbonyl groups of the triglyceride at which preferential radiolytic cleavage occurs. Scission may also occur on a random basis at the remaining carbon-carbon bonds (site f) in the fatty acid molecule. The general mechanism is summarized in Figure 1.

The most abundant radiolytic products are those formed by the scission of a single bond in the parent compound, followed by abstraction or loss of a hydrogen atom. The number and variety of such potential cleavage products from lipid radiolysis are suggested in Table 1.

The free radicals resulting from these cleavages may recombine to form additional compounds including ketones and diketones, esters, modified triglycerides, glyceryl ether diesters, alkyl propanediol diesters, butanetriol triesters, erythritol tetraesters, and various dimer hydrocarbons (diunsaturated, monounsaturated, saturated). Other radiolytic compounds are possible from multiple cleavages in the same triglyceride molecule or from the further decomposition of products from single bond scission. Hydrogenation, lactone formation, and other reactions may also occur (Nawar, 1977). It is evident that a large number of compounds are

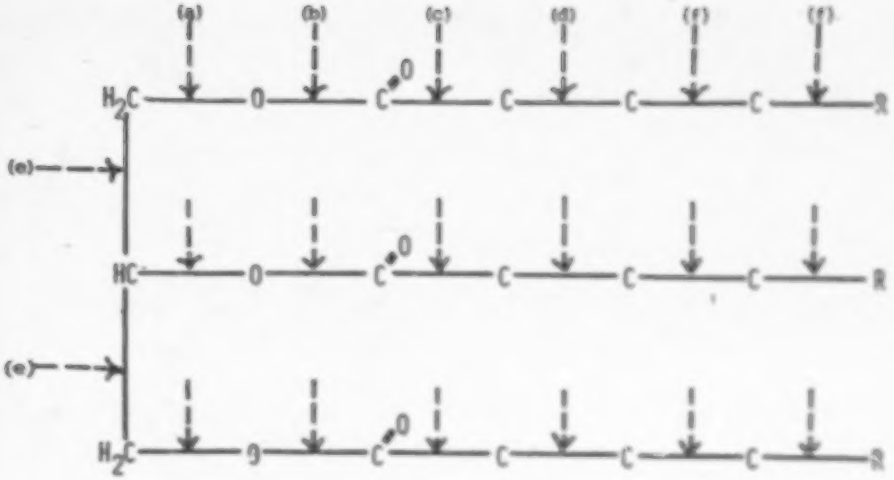

FIGURE 1. Bond scission sites of triglycerides.

Table 1. Lipid endolytic products.

Site of cleavage (See Figure 1)	Products
(a)	C_x Free fatty acids Propanediol diesters Propanediol diethers
(b)	C_x Aldehydes Alkyl cyclobutanones (C_{x-1}) Diglycerides Non-alkanediol diesters
(c)	C_{x-1} Hydrocarbons Methyl diglycerides
(d)	C_{x-2} Hydrocarbons Methyl diglycerides
(e)	Fatty acid methyl esters Ethanediol diethers
(f)	Hydrocarbons (C_{x-2}) Modified triglycerides

Higher molecular weight aliphatic hydrocarbons from the reverse recombination of free hydrocarbon radicals (Rhamy, 1978), have also been detected after irradiation of model lipid systems. Their presence in irradiated beef is assumed but has not yet been demonstrated. Since the total concentration of such recombination products was much less than of the compounds produced from single bond scission in the model systems, it is believed that the amounts in irradiated beef are probably no more than a few micrograms per kilogram.

No reports could be found concerning biological studies of such long-chain aliphatic hydrocarbons. However, these compounds are widely distributed in natural products and are present as well in oils and waxes employed in pharmaceutical manufacturing and in the processing of foods. Schuler et al. (1979) detected virtually the entire eicosane and 1-octadecene series in grapes, from decane to dotriacontane (C_{32}) and from 1-decene to 1-dotriacontene, dotriacontadiene

TABLE 2. Estimated production of fatty acids by beef irradiation.

Fatty Acid	Structure (Carbons: double bonds)	Beef Fat Composition Percent[a]	Estimated Radiolytic Production[b] (mg/kg beef: ppm)
Myristic	14:0	6.3	30
Palmitic	16:0	27.4	130
Stearic	18:0	14.1	66
Oleic	18:1	49.6	234
Linoleic	18:2	2.5	12

[a]Average composition (Deers, 1965)

[b]See text, p. 13 for calculations employed

investigators at the U.S. Army Food Sciences Laboratory (Merritt et al., 1978). Beef was irradiated at about -30°C whereas tricaproin was irradiated at room temperature. As pointed out earlier (Taub et al., 1978), irradiation in the frozen state reduces some radiolytic products by over 90 percent compared with those from liquid solutions.

Simple heating of meat liberates significant amounts of free fatty acids. Hornstein and Crowe (1960) found that each of the constituent fatty acids approximately doubled after heating beef depot fat for 4 hours at 100°C: myristic acid increased from 0.49 to 1.04 mg per g fat; palmitic acid, from 2.24 to 4.91; stearic acid, from 0.96 to 1.37; oleic acid, from 9.24 to 19.74; and linoleic acid, from 0.58 to 1.34. LeTellier and Nawar (1972a) reported that three times as much hexanoic acid was liberated from tricaproin when it was heated at 270°C for 15 hours as when it received 60 kGy (6.0 Mrad) irradiation at 25°C.

Each of the fatty acids of Table 2 is a common constituent of many vegetable and animal lipids regularly consumed in large amounts. The average diet in the United States derives about 40 percent of its calories from fat, or about 100 grams daily. Studies with isotopically labeled triglycerides indicate that approximately 40 percent are hydrolyzed to glycerol and fatty acids during digestion (White et al., 1973). Thus, the daily intake of fatty acids from normal dietary sources is several orders of magnitude greater than that possible from irradiated beef. The Joint FAO/WHO Expert Committee on Food Additives (1974) considered fatty acids to be normal products of fat metabolism and imposed no limits on their acceptable daily intake.

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*The following calculations were employed to estimate individual fatty acid production from beef irradiation. On complete hydrolysis, each molecule of tricaproin would release three molecules of hexanoic acid; one millimole tricaproin = 470 mg. Therefore, one kg tricaproin = 2,130 mmoles tricaproin = 6,390 mmoles hexanoic acid. Reported release of hexanoic acid after tricaproin irradiation = 12.20 mmoles/kg. 12.20/6,390 = 0.002 (radiolytic efficiency).

1 kg trimyristin (mol. wt. 712) = 1,404 mmoles = 4,212 mmoles myristic acid. 4,212 mmoles x 0.002 (radiolytic efficiency) = 8.4 mmoles myristic acid produced/kg trimyristin. Fat in beef is 25 percent; myristic acid is 6.3 percent of fat; 8.4 mmoles x 0.25 x 0.063 = 0.13 mmoles x 228 (mol. wt.) = 30 mg myristic acid released/kg beef. The production of the other fatty acids was estimated in a similar manner.

Of the fatty acids under consideration in this review, all but linoleic acid can be synthesized by animals. Thus, body stores of myristic, palmitic, stearic, and oleic acids reflect both their dietary intake and their biosynthesis. Linoleic acid, however, must be supplied in the diet as an essential fatty acid. Its exact role in the body is still uncertain, but its deficiency in the rat results in impaired growth, eczematous dermatitis, and impairment of reproduction (Alfin-Slater and Aftergood, 1973). Relatively large amounts can be fed without apparent harm. Swell et al. (1962) maintained 16 healthy subjects for 1 year on a high vegetable fat diet in which 22 percent of the fat calories was obtained from linoleic acid. No significant change in weights of the subjects was noted and no adverse effects were reported during the experimental period. The average serum cholesterol levels dropped from 293 to 230 mg per dl during this period. In another experiment, men were fed a diet rich in unsaturated fats for 5 years with no reported ill effects. During this period the linoleic acid of the adipose tissue rose from 11 to 32 percent of the total fatty acids (Dayton et al., 1966).

C. FATTY ACID ESTERS

Although traces of other alkyl esters of the fatty acids may be present, available evidence suggests that the methyl esters predominate. LeTellier and Nawar (1972a) detected methyl hexanoate but no other fatty acid ester, after the irradiation of tricaproin. Presumably, other esters, if present, were in concentrations below the sensitivity of the analytical methods employed. Approximately 50 mg (0.39 mmoles) of methyl hexanoate were formed per kg of tricaproin irradiated with 60.0 kGy (6.0 Mrad). Extrapolating from these limited data, the following rough estimates can be made of the methyl esters in irradiated beef: 6.5, 3.6, 1.8, 0.8, and 0.3 mg per kg for methyl oleate, palmitate, stearate, myristate, and linoleate, respectively. As pointed out earlier (p. 13), these values are apt to be overestimates because the frozen state of the beef during irradiation would reduce the amounts of radiolytic products.

The methyl and ethyl esters of each of these fatty acids have been detected in a number of natural foods (Van Straten, 1977) although their concentrations were not reported. In addition, methyl myristate is used as a flavoring agent in candy at concentrations up to 2.4 mg per kg and in beverages, ice cream, baked goods, gelatins, and puddings at levels of 0.25 to 0.50 mg per kg (Hall and Oser, 1965).

The Committee knows of no reports which specifically address the fate of these methyl esters in the body. Lipases hydrolyze acylglycerides, while simple, nonspecific esterases catalyze the scission and synthesis of esters of lower alcohols and fatty acids (Stolz, 1956). Also, a number of methylation and

demethylation reactions have been reported in normal metabolic processes (Handler and Perlzweig, 1945). Presumably the methyl esters of fatty acids would be subject to similar enzymatic action. No reports could be found of studies on the acute toxicity of these compounds. However, Alfin-Slater et al. (1965) studied effects of several methyl esters of fatty acids in short-term feeding experiments. Weanling male and female rats (USC strain), maintained on a fat-free diet were given 100 mg per day (about 2.0 g per kg at start of the experiment) of various methyl esters for 12 weeks. Rats receiving methyl myristate, palmitate, or stearate gained slightly less weight than the control animals, while those supplemented with methyl oleate or linoleate, gained more than the controls during the experimental period. Methyl oleate, but not the other methyl esters, raised the level of hepatic cholesterol esters above that obtained with the unsupplemented fat-free diet. Smith et al. (1960) fed rabbits a diet supplemented with 10 percent methyl linoleate (about 3 g per kg body weight) three times weekly for an unspecified period. There was no significant alteration in the tissue cholesterol levels. No deleterious effects were reported.

D. GLYCEROL

Only very small amounts of glycerol would be expected from the irradiation of fats, for three cleavages on the same triglyceride molecule would be required for its production. Most radiolytic products result from a single bond scission and the probability of two or more cleavages on the same molecule is low (Nawar, 1978).

Relatively large amounts of glycerol are absorbed from the normal diet. It has been estimated that about 40 percent of the ingested triglycerides are hydrolyzed to glycerol and fatty acids in the gastrointestinal tract (White et al., 1973) representing a daily intake of glycerol of about 4 g per day. In addition to its presence in natural fats, glycerol is also employed in food processing and is listed as GRAS (generally recognized as safe) in the Code of Federal Regulations [21 CFR 182.1320] (Office of Federal Register, 1977). The glycerol produced from radiolytic breakdown of triglycerides would be only an extremely small fraction of the amount absorbed from normal diets.

Glycerol is readily metabolized in the body. Gidez and Karnovky (1954) administered ^{14}C-glycerol to rats intraperitoneally, intravenously, or intragastrically and demonstrated the incorporation of labeled carbon into blood glucose, liver glycogen, and tissue lipids. Only 1 to 5 percent of the administered radioactivity could be recovered in the urine and feces. About 40 percent of glycerol was oxidized within a 6 h period to carbon

dioxide. Radioactivity was found in the lipids of most tissues examined, including the brain. The acute oral toxicity of glycerol is extremely low, with reported LD_{50} values (g per kg body weight) ranging from 7.8 to 10.0 for guinea pigs (Hine et al., 1953; Smyth et al., 1941); 19.3 to 31.5 for mice (Fischer et al., 1949 Latven and Molitor, 1939); and 27.2 to 48.5 for rats (Fischer et al., 1949; Hine et al., 1953).

Long-term feeding of glycerol to rats (Atlas Chemical Industries, 1969; Hine et al., 1953), or dogs (Food and Drug Research Laboratories, 1962) caused no treatment-related adverse effects. Male and female rats (Long-Evans strain) were maintained on diets containing 5 or 10 percent glycerol (about 5 or 10 g per kg body weight daily) for 2 years, or 20 percent (about 20 g per kg per day) for 1 year (Hine et al., 1953). No significant biochemical or pathological changes were detected. A similar study with Sprague-Dawley rats, also fed 5, 10, or 20 percent glycerol for 2 years produced no ill-effects (Atlas Chemical Industries, 1969). Dogs fed diets containing up to 20 percent glycerol (about 5 g per kg per day) revealed no pathological changes (Food and Drug Research Laboratories, 1962).

Six generations of rats were reared on diets containing 10 percent glycerol without significant influence on growth or reproduction (Guerrant et al., 1947). Administration of 1 g per kg body weight to pregnant mice or rats (days 6 through 15 of gestation) produced no significant changes from control animals in maternal or fetal survival or in the incidence of offspring abnormalities (Food and Drug Research Laboratories, 1973). Johnson et al. (1933) fed 110 g of glycerol daily (from 1.3 to 2.2 g per kg body weight) to 14 young volunteers for 50 days. No ill-effects were noted.

Glycerol has been administered both orally and parenterally in patients to reduce cerebral edema, ocular tension, or cerebrospinal fluid pressure (Tourtellotte et al., 1972). Concentrations up to 40 percent have been used intravenously without causing hemolysis.

E. MONOGLYCERIDES

Two cleavages of the same triglyceride molecule are necessary to form a monoglyceride, and since this would occur only infrequently, the amount resulting from the radiolysis of beef fat should be small. Of the five possible monoglycerides of beef, those of oleic and palmitic acids are most likely to be formed because of their greater abundance in beef fat. These monoglycerides as well as those with other fatty acids are produced during normal digestive processes in far greater amounts than could be produced by the radiolysis of beef fat. Mattson and Volpenhein (1964)

found that approximately three-quarters of triglycerides ingested by the rat were hydrolyzed in the intestinal lumen to 2-monoglycerides. The monoglycerides entered the intestinal cells intact, and were reesterified to triglycerides. Kayden et al. (1967) fed five men doubly-labeled monoglycerides and detected the radiolabel in their lymph. They concluded that the 2-monoglyceride pathway appears to be the major route of fat absorption for man during normal digestion and absorption of dietary triglyceride.

In addition to the amounts arising from normal fat digestion in the gastrointestinal tract, monoglycerides are also consumed from many natural edible oils and from various commercial preparations. Natural oils may contain up to 1 percent of monoglycerides which may increase appreciably during normal cooking processes. Approximately 0.5 percent of monoglycerides in lard and detectable amounts in bread have been reported (Kuhrt et al., 1952). A number of synthetic monoglycerides are also used extensively by the food industry, primarily as emulsifying agents. Monoglycerides of edible fats and oils, as well as certain synthetic analogues have been accorded GRAS status by the Food and Drug Administration [21 CFR 182.4521] (Office of the Federal Register, 1977).

Mattson et al. (1951) found monoglycerides to be nutritionally equivalent to di- and triglycerides of corresponding fatty acids. Weanling rats fed pure monoglycerides at a 25 percent level (about 25 g per kg per day) for 10 weeks showed no gross or microscopic pathology. Similarly, hamsters fed 5 or 15 percent of glycerylmonostearate for 22 to 28 weeks revealed no significant differences from controls in growth, food intake, or tissue changes (Orten and Dajani, 1957).

F. DIGLYCERIDES

Although some triglyceride molecules may be subjected to double or triple cleavages during irradiation, to produce monoglycerides or glycerol, respectively, they are more likely to undergo a single bond scission and leave a diglyceride residue. LeTellier and Nawar (1972a) reported the production of 2.95 mmoles (761 mg) dicaproin per kg of tricaproin irradiated at 25°C and with 60 kGy (6.0 Mrad). It was the most abundant radiolytic product identified apart from the fatty acid (caproic acid) and propanediol diester. Assuming beef to contain 25 percent fat, the diglyceride production under comparable irradiation conditions would be less than 200 mg per kg beef. Irradiation in the frozen state should yield substantially less diglyceride. Fifteen different diglycerides are possible from the five major fatty acids comprising beef fat, exclusive of positional isomers. The actual distribution of these diglycerides is unknown, but those containing oleic and palmitic acids would be expected to predominate.

Diglycerides are normally produced during digestion of fats and are readily utilized by the body. They are also used extensively as emulsifying agents by the food industry and are approved by the Food and Drug Administration [21 CFR 182.4505] (Office of the Federal Register, 1977). Many of these preparations are synthesized by direct esterification of glycerol with fatty acids, or by partial hydrolysis of natural triglycerides. The resulting mixture may contain both mono- and diglycerides as well as some glycerol, triglycerides, and fatty acids.

Relatively few reports could be found on biological aspects of natural diglycerides, presumably because their effects are assumed to be similar to the parent triglyceride. Mattson et al. (1951) fed mono-, di-, and triglycerides containing the same fatty acids to weanling rats as 25 percent of a synthetic diet. Except for slight inherent differences in caloric values, the three lipids were nutritionally equivalent. Harris and Sherman (1954) confirmed these findings with rats maintained for 70 days on an equicaloric, restricted, pair-feeding basis. Male weanling rats were fed mono-, di-, or triglycerides and various mixtures of these as 15 and 25 percent of a synthetic-type diet. All forms provided equivalent nutritive value.

G. MODIFIED GLYCERIDES

Scission of carbon-carbon bonds (sites d,f of Figure 1) of the fatty acid moieties of the triglycerides would liberate the various hydrocarbons already discussed, together with a family of diglyceride esters of varying lengths. Only the simplest of these esters, formyl- and acetyldiglycerides have been detected after irradiation of triglyceride models.

LeTellier and Nawar (1972a) reported 0.79 mM of acetyl dicaproin per kg was produced upon irradiation of tricaproin at 60 kGy (6.0 Mrad) at 17°C. If the same degree of radiolysis occurred in beef with a 25 percent fat content, approximately 100 mg acetyl diglycerides per kg beef would be produced. The concentration of formyl dicaproin was too low to permit quantitation. No information is available on the biological fate of these compounds, although hydrolysis to diglyceride and formic or acetic acid would seem likely.

H. ALDEHYDES

Cleavage of the fatty acid chain at the acyl-oxy bond (site b of Figure 1) gives rise predominantly to aldehydes with the same number of carbon atoms as the parent fatty acid. From beef fat, the following aldehydes would be anticipated: tetra-

58-005 O - 86 - 25

decanal (myristaldehyde), hexadecanal (palmitaldehyde), octadecanal (stearaldehyde), octadecenal (oleylaldehyde) and octadecadienal (linolylaldehyde). Each of these aldehydes, except for octadecadienal, was detected in irradiated beef, and was discussed in the original report (LSRO, 1977).

In the absence of air, irradiation of lipid produces only small amounts of aldehydes and ketones. The amount produced should reflect roughly the content of the fatty acid composition of the irradiated fat. Thus, oleic acid, which comprises approximately half of the fatty acids in beef fat yielded 398 µg of oleylaldehyde per kg beef after irradiation, and palmitic acid, the next most abundant acid, yielded 127 µg of palmitylaldehyde per kg beef (LSRO, 1977). Linoleic acid, comprising only 2.5 percent of the total fatty acids in beef fat would be expected to provide approximately 10 to 20 µg of the corresponding aldehyde per kg beef. However, although this estimated concentration of octadecadienal was within the sensitivity range of the analytical procedures employed, none was detected after beef irradiation *in vacuo* (LSRO, 1977).

No information on the metabolism or biological action of octadecadienal could be found. Aldehydes as a class are readily oxidized in the animal body to the corresponding acid and are normally converted by beta-oxidation to carbon dioxide and water (Williams, 1959). Alternatively, some aldehydes and ketones, especially of xenobiotic origin, may be reduced to their alcohols and metabolized accordingly (Kessler and Ferrell, 1974). Which, if either, of these pathways is followed by octadecadienal is not known.

Monty *et al.* (1961) reported the presence of small amounts of 2, 4, 5, 8, and 9 carbon aldehydes as "minor compounds" when ground meat was irradiated in a nitrogen atmosphere with 46 or 93 kGy (4.6 or 9.3 Mrad) at 20°C. Neither the exact structures of these aldehydes nor their concentrations were determined. It is assumed that they were n-aliphatic monocarbonyls. None of these aldehydes was detected by Merritt *et al.* (1972) with 56 kGy (5.6 Mrad) irradiation at about -30°C presumably because of the markedly lower temperature employed. Each of these lower aldehydes is found naturally in many foods, including meats (Van Straten, 1977). All are widely used as flavoring substances and are generally recognized as safe by the Flavoring Extract Manufacturers Association (Hall and Oser, 1965). The Council of Europe (1974) also includes them as artificial flavoring substances which may be added to foodstuffs without hazard to health. The Council has established an acceptable human daily intake for each of these aldehydes at 1 mg per kg body weight.

I. KETONES

Several aliphatic ketones have been reported after irradiation of synthetic triglycerides or meats at room temperature. Monty et al. (1961) detected 3 to 9 carbon as well as "long-chain" ketones in beef, pork and chicken irradiated under nitrogen at 46 and 93 kGy (4.6 and 9.3 Mrad). The individual ketones were not identified but were assumed to be n-alkan-2-ones. The amounts of ketones produced were not determined but the total carbonyl content (aldehydes plus ketones) in beef with 93 kGy (9.3 Mrad) was 1.01 mMoles (approximately 100 mg per kg), with more than half consisting of four to six carbon aldehydes and ketones. Three aliphatic ketones (2-pentanone, 3-hexanone, and 4-heptanone) were detected among the radiolytic products of tributyrin subjected to 500 kGy (50 Mrad) radiation in vacuo at room temperature (Meidani et al., 1977). These simple aliphatic ketones are flavorful compounds found normally in many foods (Van Straten, 1977) and often employed as artificial flavoring agents (Council of Europe, 1974; Hall and Oser, 1965).

Merritt (1972) was unable to detect these volatile ketones in beef irradiated in the frozen state. He found only acetone and 2-butanone when beef was subjected to 56 kGy (5.6 Mrad) irradiation at -30°C in vacuo. The production of cyclic ketones has also been reported after the irradiation of triglyceride models. LeTellier and Nawar (1972b) detected 2-alkylcyclobutanones of the same carbon number as the constituent fatty acid. These investigators (1972a) reported that 0.96 mM of 2-ethyl cyclobutanone per kg triglyceride (about 94 mg) resulted from the irradiation (60 kGy; 6.0 Mrad) of tricaproin at 17°C. Assuming a fat content in beef of 25 percent and the production of comparable amounts of 2-alkylcyclobutanones from the individual fatty acids in the beef fat, a production of 50 to 60 mg of these cyclic ketones per kg beef is possible upon irradiation at 17°C. The amounts resulting from beef irradiated in the frozen state are unknown but would presumably be significantly lower.

No information is available on the health aspects of alkylcyclobutanones.

J. DIOL DIESTERS

A number of diol diesters are possible from the radiolysis of fat. As shown in Figure 1 (site e), cleavage between the primary and secondary carbons of the glyceryl skeleton will produce ethanediol diesters; cleavage at the acyloxymethene bonds of the triglyceride (site a) results in propanediol diesters, which can be converted to propenediol diesters by the subsequent loss of hydrogen; cleavage at the acyloxy bond of the fatty acids (site b), followed by a loss of hydrogen would produce oxopropanediol diesters.

Each of these diol diesters was detected when tricaproin was irradiated *in vacuo* at 60 kGy (6.0 Mrad) at 17°C. By far the most abundant were the propanediol dicaproates (1,2 and 1,3) which together comprised about 85 percent of the total. Most of the remaining 15 percent consisted of ethane- and propanediol dicaproates. Traces of the oxo-derivatives (1-oxo-2,3 and 2-oxo-1,3 propane dicaproates) were also detected, but in amounts too small to permit quantitation.

An attempt has been made to estimate the amounts of diol diesters produced by the irradiation of beef. The only quantitative data available are those of LeTellier and Nawar (1972) on tricaproin irradiated at 60 kGy (6.0 Mrad) and 17°C. In extrapolating these values to irradiated beef (Table 3), it was assumed that beef contained 25 percent fat and that the fat consisted only of triolein. These simplifying assumptions do not alter significantly the estimation of *total* diol diesters although it provides no information on the content of the individual compounds. The five fatty acids comprising the bulk of the beef fat could produce 15 different diester combinations. The concentration of each diester would be a reflection of the relative fatty acid composition of the beef fat.

The calculations suggest that the total diol diester production would be approximately 1 g per kg beef irradiated at 17°C. As indicated earlier, irradiation as performed at -30°C should yield substantially lesser amounts.

The presence of diol compounds in lipid material was first reported in plant seeds in 1961 (Ukita and Tanimura, 1961). They were later detected in microorganisms (Asselineau, 1961; DeMarteau-Ginsberg and Miguel, 1962), and in mammalian tissue, when ethylene glycol was identified in hydrolysates of beef lung lipids (Carter *et al*., 1963). Since then, diol compounds have been found in the lipids of bacteria, yeast, plant seeds, invertebrates, and mammals (Bergelson, 1973). The laboratories of Bergelson in the Soviet Union and of Baumann and Schmid in the United States have been especially active in the isolation, structure determination, and biosynthesis of these substances. Bergelson and coworkers detected derivatives of 1,2-ethanediol as well as of 1,2-propanediol, 1,3-propanediol, 1,3-butanediol, 2,3-butanediol, and 1,4-butanediol in a number of bacteria, animal, and plant cells (Bergelson *et al*., 1964, 1966; Vaver *et al*., 1971). That the diol lipids may have a biological role analogous to that of triglycerides was suggested by the recovery of ethylene glycol dipalmitate from regenerating rat liver (Vaver *et al*., 1969). Subsequently, Vaver *et al*. (1972) identified three ethylene glycol diesters of heptadecanoic, heptadecenoic, stearic, and oleic acids from yeasts grown on heptadecane, indicating biosynthetic processes similar to those of triglycerides. Ethane-, propane-, and butanediols can also form the backbone of phospholipids as well as of glycolipids. Baumann *et al*. (1975) found approximately 350 µg of diol lipids per g of rat

TABLE 3. Estimated radiolytic production of diol diesters.

Compound	From triolein[a] mM/kg	From beef fat[b] mg/kg	From beef[c] mg/kg
1,2-Ethane diol diester	0.12	73	18
1,2-Propane diol diester	3.26	1967	492
1,3-Propane diol diester	2.21	1341	335
1,3-Propene diol diester	0.65	260	81
2,3-Propene diol diester	0.32	194	49
TOTALS	6.56	3821	955

[a] Modified from LeTellier and Nawar (1972a)
[b] Calculated as 100 percent triolein
[c] Assuming 25 percent fat

liver. The concentration in other examined tissues was not determined. About two-thirds of the total dose 1,2-dichloroethane metabolites, with the remaining third approximately evenly divided among the derivatives of 1,2-propanediol, 1,2-propanediol, and 1,2-ethanediol.

Little is known of the synthesis, metabolism, or physiological role of the carnosolic accounting fish tissue. Several researchers have published a series of reports on these aspects and have shown that the ovo testis can incorporate long-chain 1,2-ethanediolic into fish phospholipids (Cheng and Rumsey, 1975; Rumsey et al., 1975) as well as into glycerophosphorides (Cheng and Rumsey, 1976).

Fish-derived lecithin analogues possess strong immunization (Baer, 1953; Rumsey et al., 1980). Bergstrom (1975) speculated that in the lab concentrations found in membranes (Lucas, 1976) fish lecithins may increase the permeability of cell membranes of microbiome models (main properties).

Toxicity data (Table 6) could be found only for the oxygen dioxin. Similar data are not available for the fish diatomite problem(s) present in investigated beef and for various metabolites which might be present in small amounts.

1,3-Butanediol (BD) and 1,2-propanediol (PD) have been studied as synthetic sources of dietary calories. Bergman and Reingold (1975) have shown that the addition of BD to the diets increased the activity of liver and kidney glycosaminoglycan enzymes and the formation of ketones. Bies et al. (1975) administered up to 40 ml/kg for an indefinite amount of period to the diets of its human subjects for 10 days. Apart from a lowering of the blood glucose, no alterations of blood chemistry or cytology were noted. The investigators concluded that BD may be useful in diabetic diets. Bergman and Reingold (1975) had diets containing 5 or 10 percent BD, or 5 percent PD to obtain for 8 months. BD had no effect on blood ketones, but increased serum glucose slightly. PD, on the other hand, increased ketone bodies and reduced blood glucose slightly. They concluded that BD and PD can replace an equal part of the dietary available carbohydrate without producing untoward effects on animal performance.

[illegible]

[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]
[illegible]	[illegible]	[illegible]

V. DISCUSSION

The availability of sensitive analytical techniques has simplified the determination of volatile compounds in various media. Consequently, far more data are now available on such volatile radiolytic products of foods and model systems than on nonvolatile compounds, for which methods of comparable simplicity and sensitivity are lacking. Attempts to determine nonvolatile products have focused on simple model systems rather than on foods, so that the sites of radiolytic action could be more easily identified. Thus, in the absence of direct data on these products in irradiated beef, it has been necessary to extrapolate the findings from relatively few experiments in which substances of known structures have been used. Such extrapolations have obvious shortcomings, for not only is beef a far more complex substance than the models utilized, but other variables also influence the kind and amount of radiolytic products. Temperature, radiation dose, fat content and composition, physical status, ambient atmosphere and other factors may affect the nature and concentrations of the compounds produced. The Select Committee is well aware of these objections but believes nevertheless, that these extrapolations can provide useful information on the nature of the compounds produced in irradiated beef, and can allow a rough approximation of their concentrations.

Most emphasis in this report has been placed on the radiolytic products of the fatty moiety of beef. Considerable data are available on the radiolysis of various synthetic triglycerides, which provide a useful base for comparison with beef irradiation. Also, it has been shown that most of the volatile compounds identified after beef irradiation arose from the fatty components. Animal muscle contains only 1 percent or less of carbohydrates, mostly glycogen, which is rapidly converted to lactic acid upon death of the animal. The radiolytic products from this source would be small in amount and would consist largely of compounds containing one or two carbons found in commonly consumed foods or normally produced in the body. The primary structure of proteins can be affected by irradiation and this action is reflected by changes in their physical characteristics or biological function. A few volatile compounds, presumably arising from amino acids, have been detected in irradiated beef, but data are lacking which would permit estimations of the nature and concentrations of other simple products from beef proteins irradiated under the conditions now employed.

The major radiolytic products from synthetic triglycerides are free fatty acids, diol diesters, and diglycerides. Extrapolation of data from these model systems to beef suggests that about 1.0 g of the various diol diesters, 500 mg of fatty acids, and 200 mg of diglycerides per kg beef might be produced after irradiation. As pointed out earlier, there is evidence that

these, as well as other values obtained by extrapolation from triglyceride models may seriously overestimate the amount actually produced when beef is irradiated in a frozen state. Free fatty acids and diglycerides occur naturally in many foodstuffs, are normal digestive and metabolic products, and are authorized additions to food for desirable technical effects. The amounts produced by irradiation would be small compared with their intakes from other sources and would not be expected to have adverse health effects.

Less is known of the diol diesters, the other major product of fat irradiation. There is evidence that they are natural constituents of mammalian tissues and that they are produced in significant quantities during normal heating processes of fatty foods. Thus, tricaproin heated at 270°C for 15 hours produced ten times as much ethane dioldiester as did 60 kGy (6.0 Mrad) irradiation at 25°C. However, metabolic and toxicity data are not available on the individual members of this family, precluding any firm judgment of their possible health effects.

Based on studies with tricaproin, the only other radiolytic products present in detectable amounts were esters of fatty acids and diglycerides, aldehydes corresponding to the fatty acid components of the fat, and alkylcyclobutanones. Various aldehydes have been detected in irradiated beef in concentrations less than one part per million and were considered in the previous report to pose no hazard in these amounts to the consumer. It is believed that the esters would be hydrolyzed by gastrointestinal and tissue esterases to yield harmless levels of fatty acids and diglycerides. Nothing is known of the fate and toxicity of the alkylcyclobutanones, so no judgment can be rendered on their possible health effects.

Although relatively few radiolytic products have been detected in irradiated beef or model systems, and even fewer have been determined quantitatively, many more are possible theoretically. Many of such putative products are found in natural foods, added during food processing, produced during cooking, or present in the body as normal metabolites. As Nawar (1977) has pointed out, the nature of decomposition products formed by irradiation and heat treatment are quite similar, with many more of such compounds identified in heated or thermally oxidized, than in irradiated samples.

It is not possible to compile a complete inventory of all the components of natural foodstuffs nor of all conceivable irradiation products. The possible presence of undetected substances can never be excluded. For this reason, it is desirable to complement such chemical studies with animal feeding experiments in which the effects of irradiated and of nonirradiated beef are compared. Such experiments provide an added approach to determine wholesomeness and safety of irradiated foods.

VI. CONCLUSIONS

In the light of the foregoing considerations, the Committee concludes that:

1. Many of the radiolytic products in the concentrations estimated to be present appear to pose no hazards to consumers of beef irradiated in the described manner. Such products include the individual fatty acids and their simple esters, glycerol, mono- and diglycerides, diglyceride esters, aldehydes, and aliphatic hydrocarbons.

2. Insufficient data are available to allow judgment of the effects on health of the individual diol diesters and alkylcyclobutanones presumably present. Metabolic and toxicological studies of these compounds are desirable.

3. No evaluation can be made of other compounds theoretically possible in small amounts, but which have not been demonstrated in irradiated beef or model systems. Because no analysis, however exhaustive, can exclude the possibility of the presence of such theoretical but undetected constituents, no unequivocal demonstration of safety seems possible from consideration of individual radiolytic products alone.

4. It is desirable to couple chemical studies as described in this report with suitable animal feeding studies to provide complementary approaches to ensure the wholesomeness and safety of irradiated foods.

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REFERENCES TAKEN FROM

GAMMA IRRADIATION OF FRESH FRUITS AND VEGETABLES

AN INDEXED REFERENCE LIST (1965-1982)

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PREFACE

This bibliography was prepared as an aid to persons interested in the potential of application of gamma irradiation to fresh fruits and vegetables. It complements the following bibliography which was published in September, 1967 and covered published information through 1965 (504 titles):

> Abdel-Kader, A. S. and E. C. Maxie. 1967. Radiation pasteurization of fruits and vegetables -- A bibliography. Oak Ridge National Laboratory, Isotopes Information Center, Special Publication No. ORNL-IIC-11, 52 pp.

The bibliography is believed to be complete for titles reported in abstracting and technical journals as of December 31, 1982. It includes 648 titles which are arranged alphabetically by first-listed author followed by an author index and a subject index. Some of these titles were published before 1965 but were either missed in the original bibliography or were not available at that time in abstracting journals. Following is a breakdown in the 648 titles according to publication date:

Period	Pre 1964	1965-1969	1970-1974	1975-1979	1980-1982
Number of Titles	92	261	158	98	39

We would appreciate receiving any information concerning omissions or errors in this reference list.

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Wholesomeness of irradiated food

Report of a Joint FAO/IAEA/WHO Expert Committee

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ITS RELEVANCE TO THE ASSESSEMENT OF THE WHOLESOMENESS OF IRRADIATED FOODS

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Testimony of
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The Fusion Energy Foundation is a nonprofit educational organization located in Washington, D.C. Founded in 1974, the FEF aims to educate the public about the development of fusion energy and other advanced science and technology needed to restore American leadership in these areas.

Marjorie Mazel Hecht is the managing editor of Fusion magazine.

Testimony of the Fusion Energy Foundation on H.R. 696

The Fusion Energy Foundation is pleased to testify in support of the food irradiation legislation, H.R. 696, introduced by Congressman Sid Morrison. Food irradiation is a technology whose time has come, and it is our hope that these hearings will spur its rapid commercialization in the United States and throughout the world. We also hope that the testimony today will hurry along the long-awaited Administration approval for the new Food and Drug Administration regulations permitting food irradiation of up to 100 kilorads.

We wholeheartedly support the food irradiation legislation, and we would like to recommend the addition of two further points: First, as described below, electron beam irradiation, a spinoff of the beam defense program pioneered at Lawrence Livermore National Laboratory, is ready for immediate development and its promotion should be included in the work of the proposed Joint Operating Commission, as well as a program of incentives for the private development of electron beam irradiation. Second, also described below, we would suggest as a specific goal of the Joint Operating Commission an aggressive outreach program to transfer this technology as rapidly as possible to those countries in the developing sector that are in desperate need of ways to increase the quantity and quality of their food supplies.

We also would like to see one of the first recommendations of the proposed Joint Operations Commission on food irradiation be to bring the level and scope of the FDA regulations up to the internationally accepted standard.

The Benefits of Food Irradiation

Food irradiation is a proven technology, certainly the most researched food preservation technology today. Forty years of thorough research have demonstrated that it is absolutely safe by all scientific criteria. Its benefits are spectacular! Irradiation eliminates insect infestation, retards spoilage, extends shelf life, ensures purity, and permits shipping and storage of meats without refrigeration--all at relatively low cost.

Today in this country about 25 percent of our foodstuffs is lost to spoilage, while an estimated 50 to 60 percent of the food shipped to or produced in much of the developing sector never reaches the intended consumer because of insect infestation and spoilage. In terms of grain alone, the amount lost yearly to insects, rats, and fungi is 33 million tons--enough to feed the entire U.S. population for a year.

Saving this amount of wasted grain alone could mean the difference between life and death for millions on the continent of Africa, where an additional 17 million tons of grain per year would begin to prevent deaths from starvation. (At present, less than 3 million tons of grain a year are going to the 22 worst affected nations on the continent, and the quality of this grain is often not fit for human consumption. With food irradiation, the quality would be assured.)

It is not just human consumption that can benefit from the increase in grain as a result of food irradiation. If we are to adequately feed the world's population, we need to increase the amount of quality protein available, and this means that we need quality feed grains for animal herds. Specifically, we estimate that we need to triple the current amount of feedgrains for animals, which is now about 750 million metric tons.

The importance of providing a quality diet throughout the world cannot be overemphasized, and it is not simply a "Third World" problem. The result of starvation conditions in Africa is that the continent is engulfed in an AIDS epidemic that has already reached the United States and will begin to devastate this country, especially the urban and rural poor, whose diets and living conditions are insufficient. Worldwide, there is a desperate need for more and better food, and we need to meet this as fast as possible and by all means possible. We have to do this using all our advanced technologies from genetically engineering bacteria that will prevent frost damage, to food irradiation.

Across the board, simply by introducing food irradiation technology on a commercial scale we will immediately make it possible, without additional planting or harvesting, to increase by 25 percent the amount of food in the United States. The economy would benefit all around: The farmers would not lose their crops to insects; the food retailers would have a longer shelf life; and the consumer would have a better product and more of it. Without food irradiation, in fact, those of us in the northern United States are in danger of losing the possibility of eating citrus fruits and other tropical fruits because without adequate disinfestation measures such fruits may be prohibited from being shipped from one state to another, and the administration has now phased out the primary method of chemical disinfestation, ethylene dibromide or EDB.

The implementation of this legislation, not only would revolutionize the food industry, but also would create a boom in the U.S. export market, as the nation regained a leadership role in exporting advanced nuclear technology.

A Technology Ready for Commercialization

There is no competent scientist anywhere in the world today who questions the safety and wholesomeness of irradiated food. In fact, the United States for 37 years has led in the research on food irradiation that established the safety of the

technology. Despite this effort, which dates back to the days of World War II when the U.S. Army was investigating a way to serve palatable and nourishing meals to our troops, the United States now lags far behind the rest of the world in pursuing the development of the technology. The reasons have nothing to do with the merits of the technology; the politics of the Malthusian environmentalist movement are responsible for slowing the pace of food irradiation in the same way that they strangled civilian nuclear power in the regulatory noose.

Twenty-eight nations are now using irradiated food products--from fresh strawberries to fresh shrimp. More than 40 different food products have been cleared for irradiation with some countries, such as the Netherlands, approving 20 different foods, and Japan, a nation that has pioneered in nuclear technology, irradiating everything from seafood and seaweed to spices. Canada is aggressively pursuing the lead in exporting food irradiation technology, having built 60 of the 100 or so facilities now in operation worldwide for food irradiation and supplying 90 percent of the radiation source, cobalt-60, including that used by American firms to sterilize medical supplies. (About 30 percent of all medical supplies are sterilized by this irradiation method.)

Ironically, our existing food irradiation facilities in the United States irradiate shrimp and chickens for export only; none of this quality produce can be consumed here.

The new U.S. Food and Drug Administration regulations would change this situation, permitting up to 100 kilorads of radiation to process some foods. This maximum dose is 10 times lower than the internationally recommended standard of 1,000 kilorads adopted by the World Health Organization and the Food and Agriculture Organization in 1981. At the time, WHO wrote, "All the toxicological studies carried out on a large number of irradiated foods, from almost every type of food commodity, have produced no evidence of adverse effects as a result of irradiation."

Even at the very low dose rate of 100 kilorads, however, Americans would begin to enjoy the benefits of food irradiation: This low-level irradiation could easily kill any kind of insect in any physiological stage, compared with other disinfestation measures, which do not always eliminate insect eggs. Thus, with 20-100 kilorads, grain in storage could be disinfested, and with 20-50 kilorads, insects and insect eggs in citrus fruits and tropical fruits could be killed. At 25 to 35 kilorads, bananas, tomatoes, pears, avocados, mangoes, papaya, and other fruits could have their ripening process delayed. And at 5 to 15 kilorads, sprouting would be inhibited in potatoes, onions, and garlic.

If the FDA extends its 100 kilorad regulation to meats, poultry, and fish, there would be additional benefits: At just 20-30 kilorads, pork could be made free from trichina (the

United States now has one of the highest rates of trichinosis among advanced sector nations, and for this reason a number of European nations embargo U.S. pork products) and ground meat could be decontaminated.

At larger dose levels, of course, other crucial benefits could be provided. For example, at 100 to 300 kilorads, salmonella could be eliminated from poultry, where it now contaminates as much as half of all our chicken. It was estimated by Atomic Energy of Canada Ltd. that salmonella leads to between 10 and 15 million cases of gastroenteritis per year, and that 250 irradiation facilities could completely eliminate salmonella in poultry at a cost of just 2 cents per pound. And at even higher dose rates, 2,500 to 5,000 kilorads, food could be totally sterilized with all pathogens and viruses eliminated. With this high dose irradiation and secure packaging, food products, including meats, can stay fresh without refrigeration indefinitely. In fact, the U.S. Army testing program found that meats processed in this way were rated tasty in tests by U.S. Army personnel and retained their taste and wholesomeness when tested 10 years later. This high-dose irradiation is used to prepare the food the astronauts take with them to eat in space so that they can have a germ-free quality diet.

Refuting the Opposition

The subcommittee today will hear testimony from many experts who can document in detail the benefits of the technology and the need to rapidly commercialize it. Having studied the extensive research on food irradiation over the past three decades, we at the foundation have concluded unequivocally that the objections raised by the environmentalist lobby are capricious and without substance. Some of these objections are perhaps raised in good faith by people who don't know the answers; others are definitely raised by people who know that they are lying and misleading the public with their antinuclear propaganda.

What we are seeing is an extension of the nasty process that has beaten back civilian nuclear energy in the United States using fear as its weapon. The environmentalist lobby is trying to convince the population that advanced technologies are dangerous in general, that radiation must be especially dangerous because one can't see it, and that the people promoting new technologies are evil and only out to make money. To these environmentalists, the scientific facts do not matter. The director of the energy project of Ralph Nader's antinuclear group Critical Mass stated bluntly, for example: "We haven't had time yet to fully research the issue of irradiated food, but I have an instinctive negative reaction.... We oppose on principle the commercialization of nuclear material--whether it's Three Mile Island or smoke detectors. And I basically see this as a way of further legitimizing the weapons business."

Even those objections of the environmentalist lobby groups that are dressed in more objective clothing do not stand up to examination. These critics take one anomalous study or fact out of context and use this to condemn the entire technology. When one points out that peer reviews have determined their cited studies to be invalid, or that the study used 60 times the level of radiation proposed under the new FDA regulations, the environmentalists just keep repeating their objections. For example, the Health Research Group has trumpeted some Soviet studies against food irradiation whose authors have admitted to a top USDA food irradiation scientist that the findings were invalid because spoiled meat was inadvertently used. Similarly, the Health Research Group cites a study done in India that has been withdrawn by the institute at which it was conducted because it was invalid.

Once the scientists have answered all the objections with facts that demonstrate the safety of the technology and its benefits, the question of labeling inevitably is posed, with all the earmarks of a delaying tactic. Irradiated food should be required to sport a label indicating how it is processed, the environmentalists and others argue. Apparently it has been this question of labeling that has delayed the finalization of the FDA regulations on food irradiation. Some countries, including the Netherlands and South Africa, have adopted a small symbol to designate irradiated products. We at the foundation feel that this same symbol might be used here, but that it is not really necessary, because the process is so safe, so thoroughly tested, and leaves absolutely no radiation in the food. If the environmentalists are so insistent on such labeling are they also willing to label the so-called natural foods that they champion? How about "processed only with cow manure" or "processed with animal dung," or for grains, "protein-enriched with insect eggs."

The point is if health-conscious Americans know that their chicken is salmonella-free, that their pork is trichina-free, that their potatoes and onions will not sprout, that their chopped meat has a much lower level of bacteria, that insect eggs don't hatch in their cereal and flour, that their fruits and vegetables are insect free and will stay on the shelf longer--they will buy these products and enjoy them. The education provisions of the proposed legislation can begin the process of letting Americans know about the benefits from this technology.

The Malthusian Danger

If there is any plot involved here it is that of the environmentalist lobby and its explicit Malthusian outlook, which poses a real danger to the economy and indeed to the survival of the nation. These well-funded and self-appointed advocates of "the people" readily admit that they think the

world is overpopulated, that there are too many people, that a smaller world would be beautiful. Therefore, it is lawful that such Malthusians have no qualms about killing off millions of people by restricting the spread of technology. Opposition to food irradiation--which could potentially provide more food quickly to people who are now starving--is just one example of environmentalist behavior that directly leads to murder. These same groups have opposed the export of pesticides to the developing nations, with consequences that are staggering. One expert, an eminent entomologist, has estimated that 200 million people die per year as a result directly and indirectly of the environmentalist actions against pesticides in the United States.

In a 1982 Fusion Energy Foundation study, we calculated that 115 million people had died unnecessarily, mostly in developing sector nations, as a result of the United States slowing down the goals of the Atoms for Peace era and not spreading nuclear technology fast enough. Again, the point is that the introduction of nuclear power, an advanced technology, enables the economy to grow at a faster rate, and this increase in the growth rate provides for the increased health and well being of the population. If the 200 nuclear plants scheduled to be built between 1965 and 1980 had been built, the cheaper cost of nuclear energy and its large impact on the growth of productivity could have powered an additional 3 percent growth rate per year. Although we have not yet specifically modeled the impact of the commercialization of food irradiation technology, the same principle applies: the increase in productivity saves lives and helps the economy thrive.

The Developing Sector Market

It is important to realize that the delay in commercializing food irradiation here in the United States has greatly affected the rate of spread of the technology abroad. As mentioned, 28 countries now have some food irradiation in process, but once the United States begins to implement the technology, there will be a tremendous boom, in the developing sector in particular. Several countries in the past three years have approached the Fusion Energy Foundation for information on food irradiation and how it could be applied to their crops. They see this technology as extremely important in increasing the capability to provide protein to populations that are malnourished, where infrastructure such as refrigeration is limited, and where tropical conditions mean that food spoils fast. Fish, for example, plentiful in Bangladesh or Peru, can be irradiated raw or dried to extend its shelf life and make sure that humans, not insects get the protein benefit. These countries are not waiting for us to begin to develop the technology, but it is certain that if the United States took leadership in this area, our industry would benefit from the technology export and the recipient countries could accelerate the development of irradiation centers.

As a foundation, we have been responsible for developing programs for industrializing various Asian, African, and Latin American countries. We have centered these programs around "Great Projects," large-scale development programs that could serve as a magnet for industrializing entire regions. The Kra Canal in Thailand is one example of such a project we have advocated; the new canal through the Kra Isthmus would facilitate shipping and commerce in the Pacific Basin at the same time that it provides new sites for industrialization, along the lines of the nuplex idea from the Atoms for Peace program of the 1950s. Such agro-industrial nuplex centers are natural locations for food irradiation installations, and there are private and public sector concerns ready now to begin negotiations on this site and similar sites for joint development projects.

The potential for export is certainly one ripe for the proposed Joint Operating Commission to take on and develop, with great benefits to our industry as well.

In this context, it is also important to note the promise of electron-beam food irradiation, which is an aspect of the technology that should get immediate priority for development and commercialization. In a sense, the first-generation of food irradiation technology--cobalt-60 and cesium-137--are proven technologies, although not yet fully commercialized. Ironically,the United States has delayed so long in deploying this technology, that the second-generation is now ready for commercialization. Specifically, this is the induction linear accelerator developed as a spinoff of the beam defense program at Lawrence Livermore National Laboratory in California. This small accelerator, which can sit on top of a large desk, has the potential for providing a mass-produced, cheap, mobile, and efficient source of food processing using electron beams or X-rays. The benefits of this are tremendous. A country with limited resources might set up one mobile facility in a region and move it from crop to crop during harvest time, eliminating the need to bring the crop to the facility.

The development of this second-generation irradiation technology should in no way hinder the first wave of facilities using radionuclide sources, but it is clear that these nuclear sources would soon prove insufficient. If we were to go ahead with a crash program to commercialize food irradiation both here and abroad, we would soon find that we did not have enough cobalt and cesium as radiation sources. As the Livermore scientists calculated it, if all the cesium and cobalt available in the world were used to irradiate food, we would be able to process only 6 ounces per person in the United States--hardly enough for a crash program.

The high-power induction accelerator is not the first time that electron beam accelerators have been used for food irradiation, but it is the first time that a system has been put together that can process such large amounts of food so fast. The Lawrence Livermore program has stressed that it is not a

basic research program; that basic work has been done in the past 40 years. It is an applied research program whose purpose is to make the technology commercial in the short term. The Livermore research team has estimated the cost per machine at $1 million, with an operating cost of processing a ton of produce at 100 kilorads at $3.25 per ton. This is cheaper than the cost of processing using nuclear sources and far cheaper than the cost of using chemical fumigants.

Restoring the American System

Our nation was founded on the principle that advanced science and technology would enable the population to increase and prosper. "People are wealth," was the motto of the American System economists who recognized that the greatest resource of a nation was the minds of its citizens. In recent years, this concept has been buried by the Malthusian faction that would prefer to return to the more primitive ways of the 17th century, ditching technology and industry for a supposedly bucolic utopia where man scratches out a miserable existence using his muscles instead of machines. As we as a nation abdicated leadership in science and technology, we allowed the Malthusians and their institutions to proliferate, promoting their "appropriate technology" methods. As a result, the World Bank, the International Monetary Fund, and the Agency for International Development (AID) have been nothing but institutions for enforcing disease, hunger, and actual genocide.

There should be no illusions as to the deliberateness of this Malthusian policy to control population growth. To quote one of the more famous of the Malthusian philosophers, Bertrand Russell: "If a Black Death could spread throughout the world once in every generation, survivors could procreate freely without making the world too full. The state of affairs might be unpleasant, but what of it?" (In Impact of Science on Society).

The legislation before this committee presents an opportunity to begin to restore science and technology to its proper role as the driver for growth in our economy. An aggressive policy to develop food irradiation will revolutionize food processing, will put more and better food on American tables more cheaply. We will no longer feed 25 percent of our foodstuffs to promote the growth of insects, bacteria, and fungi. Equally important, we can export this technology to countries where it is desperately needed and wanted, countries whose leaders understand that advanced technology means that more of their people's lives will be saved from disease and starvation so that they can be productive citizens. Let there be no mistake: these developing nations understand fully that the environmentalist demands can be measured in the number of deaths these demands will cause. The developing nations do not want to import "Western environmentalism"; they want to import advanced technology.

By implementing the proposed food irradiation legislation, we can help ensure that science--not superstition and fear--becomes the basis for decision making on economic policy and that advanced technology begins to turn around the U.S. economic decline.

Lawrence Livermore National Laboratory

November 25, 1985

Mr. Tim Galvin
House Committee on Agriculture
1301 Longworth House Office Building
Washington DC 20518

Dear Mr. Galvin:

Last week I received a telephone call from Ms. Marjorie Hecht of the Fusion Energy Foundation. Ms. Hecht asked me to supplement her testimony of November 18, 1985 before the House Committee on Agriculture by forwarding additional information to you regarding my research on electrically powered radiation sources for food processing.

Please find enclosed copies of relevant research papers which describe work which I presented at the 5th International Meeting on Radiation Technology in San Diego, October 21-26, 1984 and at the International Symposium on Food Irradiation Processing in Washington, March 4-8, 1985.

Please contact me if I can be of further service.

Sincerely,

Stephen M. Matthews

Stephen M. Matthews, Ph.D.
Senior Physicist

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RADIONUCLIDE AND ELECTRIC ACCELERATOR SOURCES FOR FOOD IRRADIATION

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ABSTRACT

Radiation processing of food requires radiation sources with high intensity, penetrability, reliability, and the flexibility to be adapted to current food processing techniques. Current proposed regulations limit the radiation sources which can be utilized to radionuclides (i.e. 5.27-y Co-60; or 30.2-y Cs-137) or electrically-driven accelerators (i.e. X rays up to 5 MeV, electron beams up to 10 MeV). Therefore, the power; throughput; and use efficiency of these sources are important factors affecting the design; installation; operation; and economics of large-scale food-processing facilities. An analysis of the advantages and disadvantages of these sources is presented here, with special attention to the current status of both technologies, and with emphasis on the needs of the food-processing industry.

KEYWORDS

Food irradiation; radiation sources; present status; radionuclides; electron accelerators.

I. INTRODUCTION

The production, processing, distribution, and utilization of our food supply on a world-wide basis requires considerable management of human, technical, and natural resources. Furthermore, because of the amounts of food involved and its critical relationship to human life, any food technology innovation must be evaluated in terms of social, environmental, and economic factors. Recent U.S. Food and Drug Administration (FDA) proposed rulings (1) may soon allow the use of ionizing radiation as an alternative, or supplement to current food-processing methods. This process is known as food irradiation. Ionizing radiation is a type of radiation particle or wave capable of removing electrons from atoms, and thus producing charged atomic or molecular species, named "ions". It also produces excited atoms and molecules. For this reason, ionizing radiation is capable of initiating or inducing chemical changes. Therefore, radiation processing of food consists of simply using ionizing radiation to impart energy into food, causing minute changes in its chemical composition. These chemical changes modify or retard some physiological processes in food while also effectively eliminates or reduces the population of spoilage and pathogenic microorganisms.

Food irradiation, has been proven to be a desirable processing technique that with certain limitations, can be efficiently applied to reduce food losses; extend shelf life; disinfest fresh foods from insects; and to replace or minimize food additives (chemicals); while keeping the essential nutritional and sensory qualities of food. This technique has been studied for more than three decades in about 40 countries around the world. Since 1981, and following the report of the Joint FAO/IAEA/WHO Committee on Wholesomeness of Irradiated Food (JECFI) (2), about 25 countries have sanctioned irradiated food as safe for human consumption, and with certain limitations, have officially approved its use for more than 50 foods. However, many currently used food preservation methods (i.e. heating; chilling; freezing; air dehydration; freeze drying; concentration; chemicals; fermentation; packaging; etc.) will continue providing the basis for large-scale food preservation. Today, public health concerns on the use of some chemicals as additives, or as fumigants, have resulted in considerable urgency to minimize or replace their use. At the same time, more energy-conscious or energy-limited societies have emerged; questions on the adequacy of the world's food supply have arisen and starvation in some regions of the world has reached a crisis level. This has created an urgent need for more efficient overall processing, preservation, and distributions techniques of our food supply. Food irradiation can be used advantageously to solve some of these problems. By comparison, 2 kWh is needed to freeze 1 lb (0.45 kg) of food; and 3 kWh for canning the same amount, while only 0.5 kWh is needed for preserving it by ionizing radiation. Nitrites and ethylene dibromide (EDB) can be effectively reduced or

replaced by preserving and disinfesting food with ionizing radiation. These facts have refocussed world's attention on food irradiation as an alternate or supplemental process. Its world-wide implementation, however, will be largely influenced by economic considerations. The use of chemicals is comparatively inexpensive, energy conservation when all of the other energy requirements are considered is relatively small, and a large capital investment is needed to develop and implement the required radiation technology.

The total effect on food processed by ionizing radiation depends on several food-related factors (i.e. type, physiological stage, moisture content, environment, temperature) as well as processing factors. The most significant processing factor is the total amount of ionizing radiation energy deposited in the food. This amount is termed radiation dose, or simply dose, and is measured in grays or rads[1]. It should be noted that 1 Mrad (10 kGy) will only increase the temperature of 1 gram of water by 2.68°C, and thus the irradiation technique has been termed as a "cold" process. Its effectiveness relies on the ability of providing energy almost evenly throughout the irradiated food by means of electron interactions and an array of secondary chemical reactions. The "evenness" of this process could be compared to microwave heating which relies on a molecular resonance phenomena to transfer energy to "evenly" distributed water molecules, although microwave heating involves many orders of magnitude higher amounts of energy deposited into the food.

The general applications of food irradiation, as a function of dose are:

1) Long-term preservation (non-refrigerated) of foods such as meat and poultry, via total bacterial sterilization (high doses up to 5 Mrad or 50 kGy);
2) Reduction of microbial populations for a variety of foodstuffs (i.e. seafood) to provide product life extension (medium doses up to 1 Mrad or 10 kGy); and
3) Sprout inhibition, insect disinfestation, and/or delay of ripening for grains, fresh fruits, or vegetables (low doses up to 100 krad or 1 kGy).

The implementation of food irradiation on the scale required to process meaningful amounts of food has not yet been made; however, there is valuable experience on the use of radionuclide sources (primarily Co-60) and several types of electrical sources (i.e. particle accelerators and X-ray generators) in the radiation processing industry. The proposed FDA rules would only allow the use of ionizing radiation from two radionuclides (Co-60 and Cs-137) and from electrically-driven accelerator sources (X-radiation up to 5 MeV, and electron radiation up to 10 MeV). Higher energies and other forms of ionizing radiation, such as neutrons from reactors and/or accelerators and high-energy charged particles (protons, alphas, etc.) from accelerators, are not permitted because they can induce detectable levels of radioactivity in food. An analysis of the different radiation sources is therefore, timely and necessary.

II. RADIATION SOURCES OF IONIZING RADIATION

The differences between radionuclide and electrically-generated sources of ionizing radiation, as related to their application in food irradiation, are as follows:

1. Radionuclide (Nuclear) Sources

Radionuclide sources (Co-60 and Cs-137) are produced from private and government facilities. Greater than 95% of the world production of Co-60 resides in North America (Canada and USA), while the US government currently is the major source of Cs-137.

a) Cobalt-60 (Co-60)

Cobalt-60 is an artificially produced radionuclide with a half life of 5.27 years. It emits two equally abundant gamma rays per disintegration with energies of 1.17 MeV (100%) and 1.33 MeV (100%). It is produced in a nuclear reactor by the neutron bombardment of Co-59. Exposure of any matter (i.e. food and its package) to Co-60 does not induce any radioactivity because the energy of its emissions (average 1.25 MeV) is below the energy threshold for any gamma (photon)-induced nuclear reaction in the food-package components. Most of the experience on the irradiation of food has been gathered using Co-60 sources

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[1]One GRAY (Gy; SI derived unit) equals 1 erg absorbed per gram of irradiated matter. Traditionally, the unit of dose has been the RAD (equal to 100 erg absorbed in 1 gram of irradiated matter). Therefore, 1 Gy = 100 rad. Also 1 rad= 0.00001 Watt x sec/gram. Both units will be used in this work.

(<400 kCi) of the type to be found at large research centers. There is also limited commercial food irradiation experience with larger Co-60 facilities in Australia, Canada, Japan, South Africa, Soviet Union, and many Western Europe countries. In the USA, the radiation processing industry operates about six large Co-60 facilities (1 to 1.5 MCi), although these facilities are designed and licensed for up to 3 MCi.

b) Cesium-137 (Cs-137)

Cesium-137 is a fission fragment and therefore is a waste product of nuclear reactor operation. Cs-137 has a half life of 30.17 year which makes it significantly longer lived than Co-60. It is available in the form of doubly- encapsulated cesium chloride (CsCl). Because CsCl is highly soluble in water a large Cs-137 source constitute a potential health hazard due to the possible contamination of large amounts of water. However, experts agreed that the encapsulation of Cs-137 CsCl provides a succesfull and yet-to-fail system for the utilization of Cs-137 as a radiation source material. The gamma rays emitted by Cs-137 have an energy of 0.67 MeV, and is less penetrating than Co-60 radiation (1.25 MeV average). In water, the path required to decrease its radiation intensity to one half (half-value layer) is only 7 cm for Cs-137 compared to 11 cm for Co-60. Therefore, the use of a Cs-137 source is limited to foodstuffs that could be handled in a manner to assure a minimum/maximum dose throughout the package. The lower gamma-ray energy (than Co-60) also produces considerable absorption of the radiation within the source itself and its encapsulation which contributes to a lesser efficiency of photon use. There is no commercial megacurie Cs-137 facility anywhere in the world, and only one research source (~1 MCi) at Sandia National Laboratory, Alburquerque, N.M.

c) Food Processing Capabilities with Co-60 and Cs-137 Sources

One Million Curies (MCi) of Co-60 will process approximately 17 tons/h (~400 tons of food/day) to the 100 krad (1 kGy) when the source is used at 30% photon efficiency. By comparison, 4.57 MCi of Cs-137 will be needed for the same product-output and dosage-level capabilities. This larger amount of radioactive material is not necessarily a handicap for the use of Cs-137 because of its lower current price. As is explain below, however, there are many uncertainties on its future availability and final cost. Therefore, its commercial use is still a questionable option.

d) Present and Potential Availability of Co-60 and Cs-137

The current world supply of Co-60 is approximately 75 MCi and it is mostly dedicated to the supply and resupply of sources for medical therapy and medical product sterilization applications. If the entire world supply were to be used for food irradiation, there would be enough Co-60 to process 1,250 tons/h (~30,000 tons of food/24-h day) to 100 krads (1 kGy). On the other hand, the present world supply of separated Cs-137 is approximately 90 MCi, which could be utilized for processing of another 330 tons/h (7,900 tons of food/24-h day) to 100 krads.

The US Department of Energy (DOE) has at present, capabilities to produce approximately 2 MCi of Co-60 per year, and to transport, and commission Co-60 installations. Mini- pellets (1-mm diam.) of Co-60 are currently produced by the Atomic Energy of Canada Limited (AECL) which has a total yearly production capability of 20-25 MCi, and supplies ~ 90% of the world's needs for non-food applications. AECL, however, is planning to expand their capabilities to 60-80 MCi per year by 1990. Two US companies, Neutron Products Inc., in Dickerson, Maryland, and General Electric (GE) in Pleasanton, California, are also likely producers of Co-60 with capabilities to produce 20-30 MCi/year.

As indicated above, the present availability of Cs-137 is 90 MCi and its future availability is highly questionable. In fact, we feel that there is less potential for future Cs-137 availability than for Co-60 because the vast reserves of Cs-137 reside in unprocessed nuclear waste. The reprocessing capacity required to utilize this resource does not exist. Nevertheless, the US Department of Energy, in conjunction with the US Department of Agriculture is funding a feasibility study to investigate the use of Cs-137 for the low-dose processing of several agricultural commodities (Byproducts Utilization Program Cesium-137 Agricultural Commodities Irradiator [CACI], Department of Energy). This study is based upon the argument that the environmental problems of nuclear waste disposal could be significantly simplified if the Cs-137 were to be removed from the nuclear waste and put to a beneficial use. Even if succesfull, the amount of food that could be processed with the presently available 90 MCi in inventory would be minimal (i.e. ~330 tons/h or ~7,900 tons/day at 100 krads, 30% photon efficiency).

2. Electrically-Driven (Accelerator) Sources

A number of radiation processing applications are based on the use of various electron accelerators within the 10 MeV energy limit proposed by FDA. Most of these applications are carried out by using electron accelerators of the type and characteristics shown in table 1.

Table 1. Types and Typical Performance Parameters for Commercially Available Electron Accelerators.

Accelerator	Beam Energy (MeV)	Average Beam (kW)	Beam Type	Basis of Operation
Linear	1 to 32	0.3 to 10	Pulsed; Continuous Wave (CW)	High voltage, radio-frequency (rf) wave
Dynamitron	4.5 (max.)	up to 150	Direct Current (DC)	Cockcroft-Walton technology
Resonant Transformer	4.0 (max.)	up to 40	DC	High-voltage, insulated core transformer
Van der Graff Electrostatic Generator	3 (air) 10 (pressure tank)	low	DC	Moving belt, discharge

Average beam powers of tens of kilowatts (kW) are available now and the potential for several megawatts (MW) exists with present technology. Large, commercial scale processing of plastics (i.e. crosslinking, polymerization, grafting, cable and wire coatings) and rubber (rubber-coated wires and cables, shrinking films, and tires), as well as applications in medical-products and medical-devices sterilization, formation of foams, production of battery separators, waste treatment and soil improvements, are examples of some of the current large- scale industrial uses of electron beams.

New high-power electron accelerators with potential for large-scale commercial applications are presently being designed, tested and constructed. The capabilities of these new accelerators are summarized in table 2.

Table 2. New Electron Accelerators with Potential for Large-Scale Applications.

Accelerator	Beam Energy	Average Beam	Beam Type	Present Status
High Power RF Linac	10 MeV	500 kW	Pulsed CW	Conceptual Design
Induction	10 MeV	Megawatts	Pulsed CW	Modular Components Tested at LLNL(*)

(*) Lawrence Livermore National Laboratory.

Although some limited uses of the direct electron beams in thin foods (grain, flour) are possible, for most other uses of accelerators in food processing, converting electron beams to X rays (bremsstrahlung radiation) will be necessary. This is required because of the small penetrability of 10-MeV electrons in matter. The electron beam is converted into X rays by targeting the beam to collide with a heavy-metal converter plate as shown in fig. 1. The electron energy is changed into X-ray energy and heat, while the electron beam is stopped completely. The X rays emerge from the rear of the converter plate while the heat is easily removed by flowing water through channels within the plate. Because most (~94% at 5 MeV; ~85% at 10 MeV) of the electron energy is converted to heat, some applications of the heated water might be possible.

If the X-ray source is operated at the 5-MeV energy limit proposed by the FDA, then most of the produced X rays are emitted in a direction which is closely aligned with the original

direction of the electron beam. This "forward scattering" property of the X rays is significantly different from the isotropic (all directions) emission of gamma rays from Co-60 or Cs-137. This forward scattering also allows for a more efficient use of X rays in food processing. The efficiency of the electron-to-X ray conversion process is relatively poor and depends on the material of the converter plate and the energy of the electron beam. If Pb and a 5-MeV electron beam are used the efficiency is approximately 8%, while 92% of the electron energy is converted to heat. Because of this, an X-ray machine which can match the output capability of a 1-MCi Co-60 source (i.e. ~17 tons/h or 400 tons of food/day to 100 krads), will require a 5-MeV electron accelerator with 112 kW of beam power which will produce 9 kW of X rays (Pb converter, 8% conversion).

Critical questions related to cost and day-to-day reliability in an industrial environment are presently unanswered for most of the electron accelerators. Among D.C. accelerators, the Dynamitron, with several MeV electron beams and up to 150 kW beam power levels, is commercially available.

Recent developments in accelerator technology have resulted in a more optimistic picture for the use of high power accelerators with sufficient capability and reliability. Pulsed electron accelerators with continuous wave operation and high average beam power are being developed for nuclear physics experiments (3). This technology may prove equally viable for commercial applications (4). The US Department of Defense (DOD) has made a substantial investment in high current linear induction accelerator (LIA) for directed energy weapon research. Recent technical advances now make high-average-power induction-linear accelerators (LINACS) at low cost and high reliability a real possibility (5).

III. COMPARISON OF RADIONUCLIDE AND ACELERATOR SOURCES

a) Radiation Energy Spectrum and Directionality

Both Co-60 and Cs-137 sources emit monoenergetic gamma rays in all directions, making it extremely difficult to utilize these emissions efficiently. By properly designing these sources in multi-layers and by processing food in multiple passes and adequate depths, the overall photon use efficiency may range from 25 to 30%. On the other hand, an X-ray source which is produced with a 5-MeV electron accelerator contains a broad band photon energy spectrum covering the entire photon energy range proposed by the FDA. A comparison of these energy spectra is shown in fig. 2. The X-ray energy spectrum can be adjusted within this range by proper filtering (i.e."hardening") to provide a more penetrating radiation than is possible with either radionuclide source. As shown in fig. 2, the average energy of the hardened radiation increases from 1.06- to 1.6-MeV, when using a 0.25-in. thick Pb filter (absorber). However, this can be accomplished only at the expense of about half of the field intensity. The X-ray intensity loss can be compensated with an increase in electron beam power, provided that extra power is available from the electron accelerator. Induction linear accelerators have the potential to provide the needed megawatts of beam power. The forward scattering of the radiation results in a lower radiation field divergence (or loss) and amounts to a direction-oriented beam, which results in a more efficient photon usage.

b) Steering Capabilities

Because the X rays are produced at the position where the electron beam collides with the metallic converter plate, the precise location of the collision and resulting radiation source can be controlled by steering the electron beam with electromagnets. This can result in shaping the geometry of the electrically-produced radiation field to accommodate different size packages while maintaining high photon-use efficiency. There is no such capability with radionuclide sources.

c) Operational Reproducibility and Versatility

An electric source is not subject to the temporal variations which occur with the decay and periodic replacement of a radionuclide source. Therefore, specific written procedures for achieving each technical effect in a specific food item can be easily described and reproduced based upon specific treatment protocols. However, electrically generated X ray sources have the potential of significant variations due to changes in operational parameters. Beam energy, beam current, repitition rates, scan width, etc. are some of the variables that must be accurately controlled in order to maintain the operational and output characteristics of the accelerator. A program for monitoring these variables, and for

ensuring compliance to set standards is required. Because of its longer half life, changes on a time-basis are smaller with Cs-137 (30.17 y) than with 5.3-y Co-60. The latter would require greater periodic adjustments of treatment rates to account for its decay. In the case of electron accelerators, the x-ray converter plate can be removed making the electron beam itself available as a radiation source for many specifically thin-packaged foods and other non-food applications.

d) Depth-Dose Distributions in Food Packages

The ability to process large amounts of food with intense ionizing radiation depends upon both the total radiation dose and on the dose uniformity which the food requires to obtain the desired technical effect. The different energy spectra available with Co-60, Cs-137 and X rays from a 5-MeV electron beam result in large variations in the dose uniformity attainable within a package. This is illustrated in Fig. 3 for each of these sources assuming a 2-feet thick package is filled with food of 0.75 g/cm^3 density. The penetration and lower divergence of electronically-produced X rays combine to produce a superior dose-uniformity ratio that is unattainable with either Co-60 or Cs-137 sources.

Table 3 also illustrates this point by listing values of relative dose at various locations inside the package for several different food densities. These calculations do not include the effect of the packaging material which would enhance the depth-dose differences, or the dose build-up, which would minimize these differences. The effect of these factors is under investigation.

Table 3. Relative Radiation Dose As a Function of Food Density Between Two Radionuclide or Converter Plates Sources Separated by 2 Feet.

Distance From Plate	Radiation Source Type: Radionuclides Cs-137	Radionuclides Co-60	Bremsstrahlung 5-MeV	Bremsstrahlung (5 MeV Machine Rectified) 5-MeV
	Food Densities 1.0, 0.75, 0.6, (top), and 0.5, 0.3 (bottom) g/cm^3.			
1 cm	96.6 68.4 27.0	62.7 23.0 16.3	13.5 6.13 5.07	10.4 6.56 6.05
(0.0033 ft)	19.5 18.2	12.8 7.96	6.71 3.99	6.08 3.69
0.1 ft	23.4 12.2 8.23	11.9 6.95 5.51	6.66 4.27 3.39	5.35 3.62 2.85
	6.35 3.83	6.57 3.58	2.75 1.61	3.67 1.78
0.2 ft	12.2 7.68 5.67	6.95 4.61 3.63	4.36 3.18 2.59	3.76 2.73 2.23
	4.80 2.69	3.11 2.32	2.17 1.43	1.96 1.52
0.3 ft	7.67 4.64 3.51	4.57 3.24 2.65	3.13 2.39 2.01	2.81 2.16 1.84
	2.93 2.09	2.35 1.86	1.69 1.44	1.64 1.37
0.4 ft	4.79 3.23 2.59	3.19 2.42 2.07	2.38 1.92 1.68	2.18 1.76 1.57
	2.23 1.71	1.87 1.57	1.54 1.30	1.45 1.25
0.5 ft	3.21 2.35 1.97	2.33 1.89 1.67	1.86 1.55 1.40	1.75 1.48 1.27
	1.77 1.45	1.55 1.36	1.35 1.20	1.30 1.17
0.6 ft	2.24 1.78 1.57	1.77 1.52 1.40	1.52 1.31 1.27	1.45 1.28 1.23
	1.45 1.27	1.33 1.22	1.21 1.12	1.18 1.10
0.7 ft	1.63 1.41 1.30	1.48 1.27 1.21	1.27 1.15 1.14	1.24 1.17 1.12
	1.24 1.15	1.18 1.12	1.13 1.07	1.10 1.06
0.8 ft	1.26 1.17 1.13	1.17 1.12 1.09	1.13 1.09 1.08	1.10 1.07 1.05
	1.10 1.06	1.08 1.05	1.05 1.03	1.04 1.03
0.9 ft	1.06 1.04 1.03	1.09 1.03 1.02	1.03 1.02 1.01	1.03 1.02 1.01
	1.03 1.02	1.02 1.01	1.01 1.00	1.01 1.00
1.0 ft	1.00 1.00 1.00	1.00 1.00 1.00	1.00 1.00 1.00	1.00 1.00 1.00
	1.00 1.00	1.00 1.00	1.00 1.00	1.00 1.00

(*) For all food densities, doses are normalized at midpoint between plates.

e) Compatibility with Existing Food Processing Technology

Electrically-driven accelerators are in principle more compatible with existing food processing equipment. The addition of an X-ray irradiator into an already existing food processing facility presents far fewer problems than would the introduction of a multi-megacurie radionuclide source. The latter would require massive, permanent, all-directions shielding to protect workers and the environment. On the other hand, electrical accelerators only require that the shielding be positioned when the system is in

operation. The X ray's forward-scattering characteristic may also result in less on-site overall-shielding requirements because the beam's directionality allows a better selection for placement of the accelerator while also allowing reduced shielding in other directions. This latter aspects also enhances the advantages for portable systems (see below). An electrically-driven radiation source on/off capability is also an important safety feature in cases of system failure or in instances of product-handling problems.

f) Potential for Portability

A portable, truck-mounted electrically-driven radiation source with the throughput equivalent of several megacuries of Co-60 would be very desirable because of the flexibility of operation which it would provide. Because of the shielding requirements, a "portable" type radionuclide source capable of high processing throughput is extremely unlikely, although a Mobile Gamma Irradiator (MGI) loaded with 80,000 Ci of Co-60 (June 1966), and mounted on a 40-foot heavy-duty trailer-jeep was operated at the University of California-Davis (6). The MGI facility had a dose rate capability of 500 krad/h and was capable of processing 360 kg/h of strawberries at 100 krads. On the other hand, the design and engineering of a portable electrical source with high output has not yet been made. In 1970, however, a 200 keV; 150 mA X-ray facility was mounted aboard the fisheries research vessel "Anton Dohrn" and operated by the Federal Research Centre for Fisheries, Hamburg, West Germany. The maximum throughput is 60 kg/h at 100 krads. Despite of this,the potential use of portable accelerators for other beneficial uses in agriculture (i.e. soil sterilization in addition to food processing) makes this option worth exploring. A schematic of the design features of a two-sided accelerator is shown in fig. 4. An artist rendition of a food processing facility and its underground irradiation zone is shown in fig. 5A (general view) and fig. 5B (close view).

IV. CERTAIN SELECTION CRITERIA FOR IRRADIATION SOURCES

a) Logistics and Public Concerns of Radionuclide Sources Operation

There is not enough Co-60 and/or Cs-137 available to process meaningful quantities of food. The 1982 US orange crop was approximately 9.5 million tons (26,000 tons/24-h day on a yearly basis). If all this tonnage were to be treated over a 5-month period, it would require 150 MCi of Co-60, or 722 MCi of Cs-137. These amounts represent 2.11 and 8.02 times the present world's inventory of Co-60 and Cs-137, respectively. Significantly higher supplies of Co-60 and/or Cs-137 sources will be required to treat other foods, even if only a small fraction is treated. New nuclear reactors and an increased nuclear-waste processing operation would be needed. The latter would also result in approximately 1.85 times the radioactivity of other major fission products (radioactive waste) for every megacurie of separated Cs-137. A significant modification of current public attitude on expanding the US nuclear industry would also be needed.

Despite the excellent safety and operational record of multi-megacurie radionuclide facilities presently in use by the radiation processing industry (non-food applications), public acceptability of the proliferation of large, centrally located radionuclide facilities within major food distribution centers is seriously in doubt. Even if the public is willing to accept these facilities, and because the presently operating electrical-power reactors are not adequate for Co-60 production, it would be necessary to construct new nuclear reactors with adequate neutron fluxes for the production of Co-60. This would also require an increase in Cs-137 processing capabilities. Today, there are clear indications that the public will largely opposed both of these requirements.

If food irradiation is based on radionuclide sources, then the smaller harvester or processor may not be able to take advantage of the technology due to economics, technical, and environmental considerations. This food would have to be processed in large centralized facilities. This would require additional transportation and storage capabilities, and may result in increased food losses due to mechanical damage, greater losses due to spoilage of these highly-perishable foods, and in added cost to consumers.

b) Public Acceptance

Once the proposed FDA rules become effective, public acceptance of food irradiation will largely depend upon issues of worker's safety, fear of radiation, potential for terrorism

and accidental dispersion of the source material, and on clear understanding of the benefits, economic cost, and risks. Although public acceptance in the US is still an open issue, it is reasonable to assume that this issue will present a less severe problem if an electric rather than a radionuclide (nuclear) radiation source is used.

Electrically-driven sources must then be considered as a desirable alternative to radionuclide sources. At the very least, electrical sources will not have to bear the stigma of a nuclear technology, nor have the requirement of satisfying many of the legitimate environmental and safety concerns associated with the production, transportation, installation, maintenance, operation, resupply, and disposal (storage) of radionuclide sources.

c) Some Economic Criteria

A full economic evaluation of the implementation of food irradiation is beyond the scope of this work. However, it is necessary that some of the economic parameters needed to compare costs of using radionuclide or electrical sources be clearly identified. A more detailed economic evaluation of these sources is given by Lagunas-Solar and Matthews (7).

At present, the cost of Co-60 is approximately US $1.00/Ci. This price does not include transportation and installation costs. Because Co-60 manufacturers will have to expand their production capabilities, the price of Co-60 is expected to rise many times. High specific activity Co-60 is already US $ 3-4/ Ci and therefore, it is likely that the new prices will reach that range. A 1 MCi source of Co-60 could very well cost in the 3-4 million dollar range (without transportation and installation costs), and would require periodic resupplying to maintain its output capabilities.

The physical characteristics of Cs-137, with less penetrating gamma rays (0.662 MeV vs. 1.25 MeV for Co-60) will limit its applicability, while present and future limited supply will greatly curtail its large scale use. The US government is the sole producer of Cs-137, and is likely to loan or lease megacurie Cs-137 sources, thus reducing the cost of the radiation source. However, because 4.57 MCi of Cs-137 are needed in order to match the output capability of 1 MCi of Co-60, transportation and installation costs of the larger amount of radioactive material will largely offset the saving on the source-material acquisition. Because of its longer half life of 30 years, resupply cost of these facilities can be reduced.

Some electron accelerators with output capabilities equivalent to 1 MCi of Co-60 or 4.57 MCi of Cs-137, are presently being cost-priced in the 1 to 1.5 million dollars. Design, engineering, construction, and maintenance of electron accelerators are, however, likely to be a very competitive domain of multiple sectors of the private industry. This is the opposite scenario likely to exist with the radionuclide-source industry, and should result in better systems and reduced future costs. Accelerators with versatility of operation (food and non-food applications), portability, reduce shielding needs, and on/off operation can also result in increased use efficiency.

Higher energy and beam power accelerators (5-10 MeV, > 50 kW) are required for an economical and competitive food irradiation technology. Therefore, of the many types of accelerators the linear accelerators are the likely choice for most applications. Current innovations and developments are based upon the use of solid-state components and microcomputers, and have resulted in improved reliability (98-99%); greater efficiency in the utilization of electrical power and in its conversion into beam power; simplified construction and control functions. Induction linear accelerators (ILA) are becoming extremely attractive due to their potential for generating high intensity beams with high average beam power (kW to MW). Because of both latter features and due to the pulsed nature of the electron beams from ILA, the dose rate achievable can be as high as 10^{14} rads/sec, compared with approximately 10^{4} rads/ sec estimated from a several-megacurie Co-60 source. The significant difference in dose rate capabilities suggest that some of the undesired side reactions in food irradiation that have been observed with radionuclide treatments may be suppressed with the ultrashort exposure characteristics of ILA. Although this "suppression effect" has been observed in studies of the radiolytic effects in very dilute solutions, there are few experimental observations with food (mostly beef), and none to our knowledge with fresh fruits and vegetables.

V. CONCLUSIONS

It appears that electrically-driven electron accelerators are at present the best choice as radiation sources for food irradiation. However, these sources need to be further developed to achieve optimum efficiency. For furthering the implementation of electrical accelerators, several scientific and technical challenges remain and must be solved in the near future. These are:

a) the development of electrical sources based upon up-to-date technologies;
b) testing of these high-power electrical accelerators against the existing data-base obtained with radionuclide sources (mostly Co-60);
c) transfer of this technology to the private sector;
d) the design of irradiation systems that are efficient, safe, and fully integrated with current food processing facilities;
e) the development and documentation of treatment protocols per commodity to assure efficacy (i.e. total-dose, dose-rate, and dose-uniformity measurements, physiological and physical parameters, treatment rates, combination technologies, etc.); and
f) an effective public (consumer) education effort to demonstrate the potential of this technology, and create a sensible balance between benefits and risks.

Because of present needs, the initial uses of food irradiation are likely to take place with either radionuclide and/or current electrical radiation sources. The success or failure of these original ventures will greatly influence the future large-scale use of this technology on a world-wide basis. An effort to properly recognize the advantages and current limitations of the available radiation sources is, therefore, necessary from the onset. This is the main goal of the present work.

ACKNOWLEDGEMENTS

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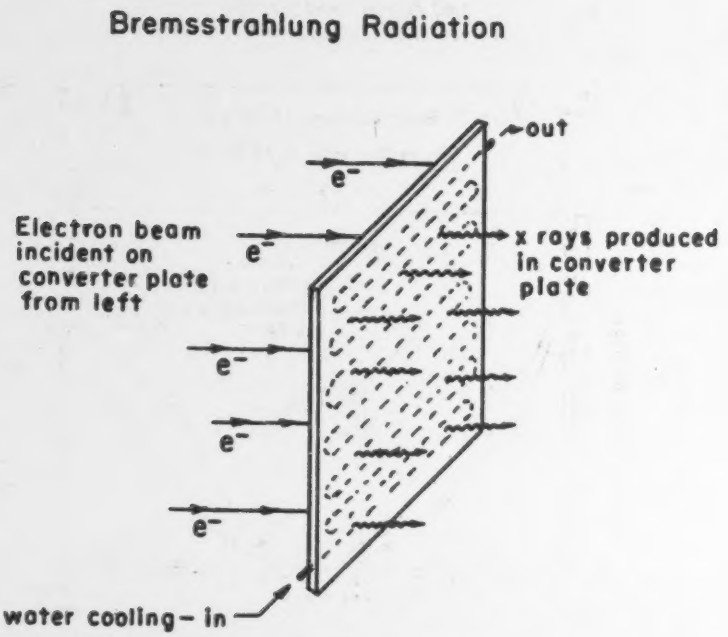

Fig. 1. Electron-to-X Rays (Bremsstrahlung) Conversion.

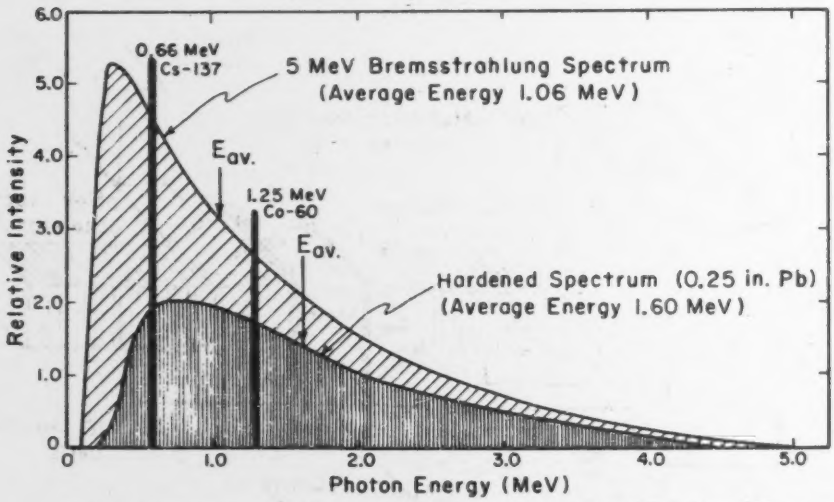

Fig. 2. Comparison of Photon Energy Spectra for Co-60 and Cs-137 Radionuclide Sources with X Rays (Bremsstrahlung) Spectra (Filtered and Unfiltered) from a 5-MeV Electron Accelerator.

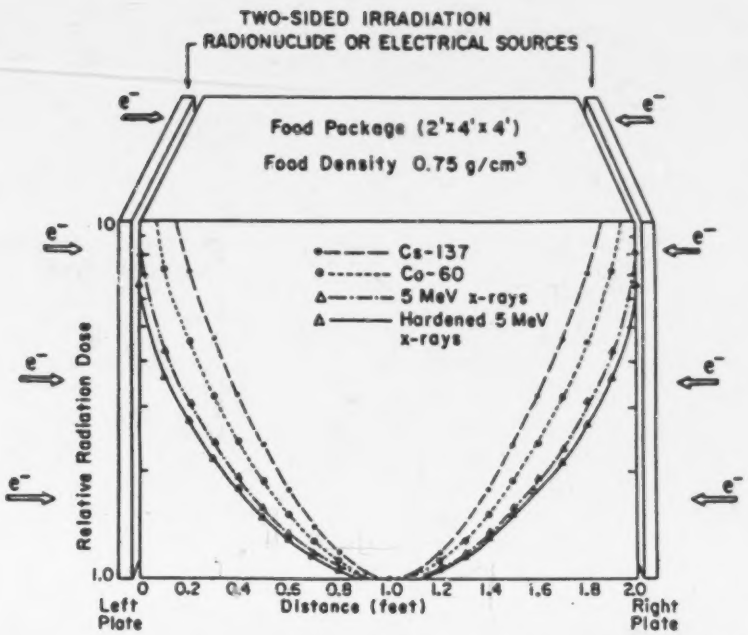

Fig. 3. Comparison of Dose-Depth Ratios for Co-60 and Cs-137 Radionuclide Sources with Filtered (Hardened) and Unfiltered X Radiation from a 5-MeV Electron Accelerator, on a 2x4x4 ft Food Package (0.75 g/cm^3).

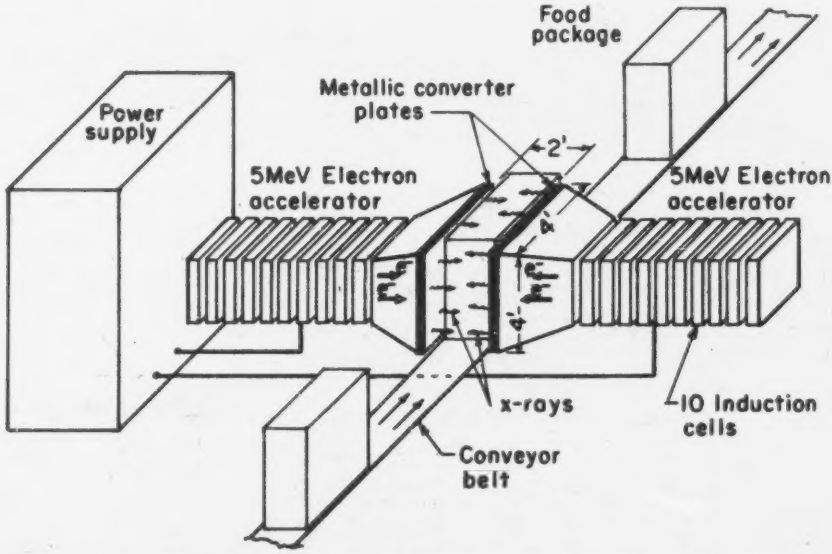

Fig. 4. Schematic of a Two-Sided Linear Induction Electron Accelerator.

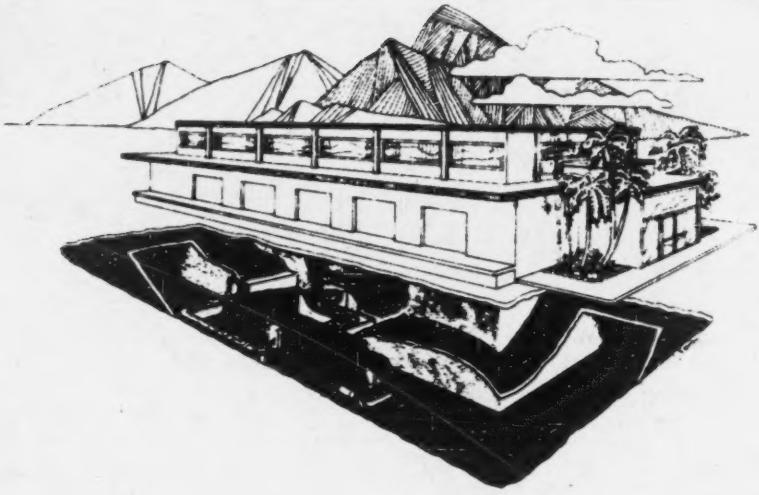

Fig. 5 A. General View of an Underground Food Irradiation Facility Using a Portable Two-Sided 5-MeV Electron Accelerator.

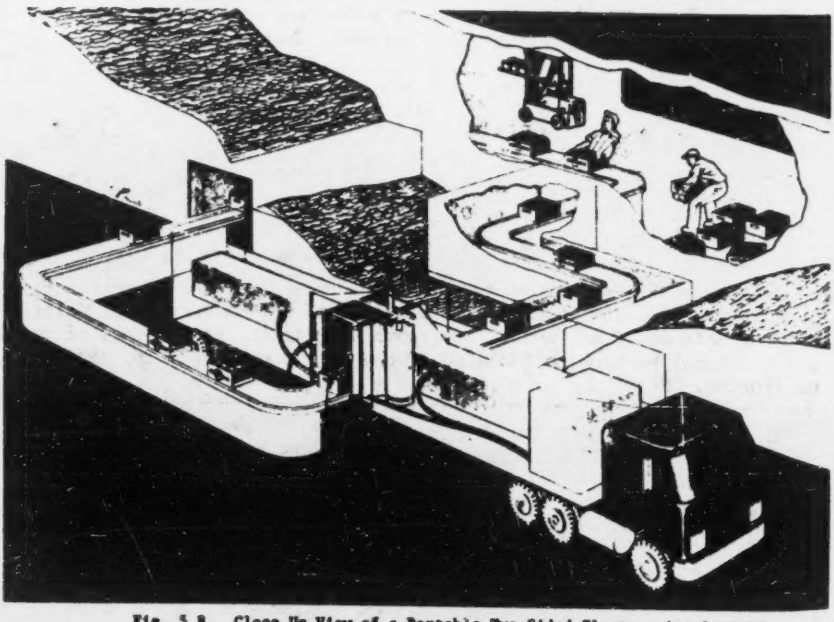

Fig. 5 B. Close Up View of a Portable Two-Sided Electron-Accelerator Food Irradiation Facility. The Facility Uses Soil and Concrete as Primary Radiation Shielding.

COMPARATIVE ECONOMIC FACTORS ON THE USE OF RADIONUCLIDE OR ELECTRICAL SOURCES FOR FOOD PROCESSING WITH IONIZING RADIATION

by

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COMPARATIVE ECONOMIC FACTORS ON THE USE OF RADIOISOTOPE OR ELECTRICAL SOURCES FOR FOOD PROCESSING WITH IONIZING RADIATION

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Introduction

If irradiation processing of food is to come out of the laboratory and into the commercial world it will be necessary to provide numerous processing facilities each with a throughput of the order of 100 MRad Tons/day. This processing rate is equivalent to processing 42 metric tons per hour at the 100 kRad dose limit proposed by the FDA for most foods as a fumigant replacement and shelflife extender.

In order for irradiation processing of food to proceed at the rate of 100 MRad Tons/day it is necessary to use an intense source with an output of tens of kilowatts of ionizing radiation. The FDA has proposed four types of sources. Two are the radionuclides cesium-137 and cobalt-60, which each emit gamma radiation. The remaining two sources are electrically produced. These are x-ray

devices with photon energies up to 5 MeV, and electron sources with beam energies up to 10 MeV. Both of these sources require an electron accelerator.

Each of these four radiation sources has different physical characteristics which give rise to economic constraints limiting their commercial application to food processing. This paper will compare these characteristics and examine some of the economic consequences which result with a particular source choice. The characteristics of each of these sources is listed in Tables 1-4.

I. RADIATION SOURCE CHARACTERISTICS

Cesium-137

Cesium-137 is a waste product formed within a nuclear reactor as a by-product of the fission reaction. It is obtained by chemically reprocessing spent reactor fuel rods to separate the cesium from other radioactive wastes. The separated cesium is used in the form of cesium chloride, a water soluble salt which is encapsulated within a triple steel liner. A 1000 MW nuclear reactor operating for one year will produce approximately 4 megacuries (4 MCi) of unseparated cesium-137.

The size of a radionuclide source is measured by the number of nuclei disintergrating per second within the source. One megacurie (abbreviation MCi) means 3.7×10^{16} disintergrations per second.

Cesium gamma radiation is at a photon energy of 0.66 MeV. The photon energy determines the penetrability of the radiation through food and cesium produced radiation is not particularly penetrating. If a pallet size volume 4'x4'x2' is filled with 1200 lbs. of fresh produce and placed between two 4' square cesium source plates separated by a gap of two feet, the pallet will be irradiated through both square sides. The maximum to minimum dose ratio produced by exposures at either surface and at the pallet center will be 27 to 1.

The use efficiency of cesium radiation is not high due to its poor penetrability. Only 66% of the produced radiation is able to escape through the steel liner containing the cesium chloride. The use efficiency of the available radiation depends upon the thickness and density of the processed food package and its distance from the source. Overall, a cesium use efficiency of 20% is considered good for food processing.

The widescale use of cesium for commercial irradiation processing would partially alleviate the nuclear waste disposal problem. Furthermore, it makes good economic sense to find uses

for waste material. For these reasons, the U.S. Department of Energy (DOE) will sell encapsulated cesium chloride for $100,000 per MCi. Since cesium-137 has a halflife of 30 years, a given quantity of the isotope will decay at a rate of 2.28% annually.

If cesium is used as a food processing source at 20% efficiency, then 17.4 MCi would be required to process at a throughput of 100 MRad Tons/day. This amount of cesium is much larger than any present single cesium source and is an appreciable fraction of the world supply of cesium chloride which currently totals 90 MCi. Additional cesium would be available from existing nuclear waste stockpiles provided more chemical separation facilities are built.

Cesium has been suggested as a source for processing pork carcasses which have first been split in half to decrease their thickness.[1] The pork will be processed to a minimum dose of 25 kRad to eliminate trichinosis while maintaining a max/min dose ratio no greater than 4 to 1 to avoid exceeding the 100 kRad FDA limit. The cesium use efficiency for pork processed in this manner will be less than 5%.

Cobalt-60

Food irradiation has been researched for more than thirty years and utilized commercially for over ten years. Practically all of this cumulative food irradiation experience has been with cobalt-60 sources. Therefore cobalt is favored as a choice for food irradiation.

Cobalt-60 is produced by placing natural cobalt metal within the core of a nuclear reactor where it is exposed to a neutron fluence which converts the natural metal into the radionuclide. The cobalt, in the form of small metal slugs, is encapsulated within a steel liner for use as a source of radiation. A large power reactor can be used to simultaneously produce electricity and cobalt-60 at a rate which depends upon the design of the reactor and the manner in which the natural cobalt is placed within the core. Cobalt-60 production rates of approximately 3 MCi per year per reactor are reasonable limits for commercial power reactors.

Cobalt-60 gamma radiation consists of two photon energies, each with an energy close to 1.25 MeV. Since the cobalt photon energy is approximately double that of cesium, the cobalt radiation is considerably more penetrating. The sample 4'x4'x2' pallet filled with 1200 lbs. of produce and irradiated through

both square faces would experience a max/min dose ratio of 16 to 1 if a cobalt source is used. This is a considerable improvement over the 27 to 1 ratio achievable with a cesium source.

The superior penetrability of cobalt radiation, as compared to cesium radiation, results in a better use efficiency and a more uniform dose distribution throughout the irradiated sample. A cobalt food processing facility can achieve use efficiencies of up to 30% with proper management. Furthermore, a megacurie of cobalt radiates at 4.5 times the power radiated by a megacurie of cesium. The higher output power, better penetrability and increased use efficiency of cobalt, as compared to cesium, result in a cobalt source requirement which is less than one sixth that of cesium to process food at the same throughput. If cobalt is used at 30% efficiency then 2.6 MCi are required to achieve 100 MRad Ton/day throughput. Commercial irradiation facilities with this amount of cobalt are in operation today.

Cobalt-60 can be purchased from several nuclear source supply companies, however AECL in Ottawa produces approximately 90% of the 80 MCi world's supply. AECL sells steel encapsulated cobalt at a price of $1 million per megacurie. This is ten times the price of cesium. Cobalt-60 has a halflife of 5.3 years, therefore it decays at an annual rate of 12.39% which is more than five times the decay rate of cesium.

Cobalt is presently in very short supply because of the current non-food processing uses. Much of the demand for this nuclide arises from the need to replenish existing sources. There are long delays between initial purchase order and cobalt delivery. Each new unit of supplied cobalt creates additional annual demand because of the rapid cobalt-60 decay rate.

5 MeV X-rays

X-rays are produced when electrons are stopped in a metal converter plate as shown in Figure 1. The process of stopping the electrons converts their energy into x-rays and heat. The heart of the x-ray source is the electron accelerator which supplies these electrons. If the energy of the supplied electrons is 5 MeV then a broad spectrum of x-ray photon energies is produced with a maximum photon energy of 5 MeV.

5 MeV x-rays have a use efficiency of better than 50% however, they are inefficient to produce. Approximately 8% of the electron energy is actually converted into x-rays. The remainder is converted into heat which is removed by flowing water through the converter plate. A 1 MW accelerator can provide 150^{15} watts as a by-product at a rate of approximately one million per second.

The recent ability to build commercial grade electron accelerators with very high average power outputs has made 5 MeV x-rays a promising processing mode.

About half of the electrical energy supplied to a facility is effective in accelerating the electrons. The remainder of the electric power is required to drive ancillary equipment such as power supplies, electromagnets, and vacuum pumps.

A 5 MeV electron accelerator which produces 1 MW of electron beam power will require approximately 2 MW of electric input power. This accelerator would produce sufficient x-rays for food processing at a throughput of 346 MRad Tons/day in spite of the 0% conversion efficiency. In order to match this performance 9 MCi of cobalt or 60 MCi of cesium would be required.

The 5 MeV x-ray spectrum is more penetrating than the radiation from either cobalt or cesium. Furthermore, the penetrability of these x-rays can be increased by filtering the radiation before it is applied to the food. The filter will preferentially remove the lower energy photons leaving the remaining x-rays enriched in higher energy, more penetrating radiation. The process of increasing the penetrability of x-rays by filtering is called "hardening" the radiation. Hardening produces a more uniform dose distribution within the irradiated

sample at a cost of reduced use efficiency. Cobalt and cesium radiation can not be hardened.

We compare the max/min dose ratio produced by 5 MeV x-rays to the ratios discussed earlier produced with cobalt and cesium radiation applied to a sample 4'x4'x2' pallet filled with 1200 lbs. of produce and irradiated through the 4' square sides. The resulting max/min dose ratio using 5 MeV x-rays is 5.9 which is a considerable improvement over the corresponding ratios achieved with either cobalt or cesium. Furthermore, the max/min dose ratio can be improved to 4.9 by first hardening the x-rays with a 1/4 inch thick lead filter. This improvement in dose uniformity would reduce the use efficiency to 60% of the unhardened x-ray use efficiency.

X-ray sources have not been widely used for food processing in spite of their high penetrability, use efficiency and convenience. The reasons for this are the lack of readily available high average power electron accelerators that have the required commercial reliability and cost.

It is difficult to consider food irradiation processing on a large commercial scale without the use of 5 MeV x-ray generators. If the present world suppply of both cobalt-60 and cesium-137 chloride were devoted entirely to continuous food processing at the FDA approved 100 kRad limit, then the combined throughput

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would be 1500 metric tons per hour. This throughput, which is less than 6 oz. per day per US citizen, could be matched by ten 5 MeV x-ray generators costing approximately $1 million each.

Induction Linear Accelerators

Induction linear accelerators are the least complex, most rugged of all high power accelerators. Their modular design enables a series of identical accelerating stages to be linked together to boost the electron beam to the desired voltage. Their mechanical construction tolerances are simplified because their accelerating principle does not require a resonant cavity. They are tolerant of relatively poor quality vacuum systems because only modest voltages are present along the accelerating stages inside the machine. Recent advances in magnetic switch technology have made these accelerators capable of very high average power at a commercial cost.

One such accelerator has recently been built at the University of California Lawrence Livermore National Laboratory.[2] The Livermore accelerator uses four modular, cylinderically shaped accelerating stages which each boost the electron beam energy by 0.5 MeV. The output beam has an energy of 2 MeV with an average power capability of 1 MW. Each modular

accelerating stage is 34 inches long and 30 inches in diameter. This accelerator will be used to study x-ray processing of fresh produce under a University of California program with the Davis and Livermore campuses.[3]

A 5 MeV x-ray source for food processing has been considered using existing hardware designs from the Livermore machine. A conceptual sketch of this source is shown in Figure 2. It consists of two coaxial 5 MeV accelerators with a 2' wide x-ray zone between them for processing pallet sized containers.

The small size of the radiation zone simplifies shielding and ozone ventilation and increases the feasibility of inert atmosphere processing.

The approximate Livermore costs to replicate these components to build the design of Figure 2 are listed in Table 5.[4] At present there are no commercial manufacturers of induction linear accelerators. The price at which an accelerator of this type could be built, by those unfamilar with this technology, is not known. The costs listed in Table 5 are assumed to be representative and will be used in the comparison analysis between electric and radionuclide radiation sources.

10 MeV Electron Beams

Electron beams can be used directly for food processing without conversion into x-rays. The FDA will allow direct electron irradiation of food at energies up to 10 MeV. Direct electron beam processing at use efficiencies of 60% are achievable with no conversion penalty imposed upon the user, as is the case when the electron energy is converted into x-rays.

However, electron irradiation is much less penetrating than the gamma and x-ray photon irradiation described earlier. Electron irradiation is suitable for processing food samples no thicker than several inches, even at the maximum 10 MeV energy allowed by the FDA. Nevertheless, electron beam processing is ideally suited for thin food samples such as packaged luncheon meats or grain.

The accelerator power requirement for electron beam processing is considerably less stringent than is the power requirement for x-ray processing. A throughput of 100 MRad tons/day can be achieved with beam powers of less than 0.02 MW. Commercial electron accelerators are available at this power level, but with energies below 10 Mev. They have enough reliability at an effective cost such that electron beam processing of food is entirely feasible within the limits imposed

by the small penetrability of this radiation. Because of both the small penetrability of electron beams through food and the minimum power requirements demanded of the accelerator, processing with this radiation must be considered apart from processing with the three photon sources discussed earlier.

If a 1 MW induction linear accelerator were used to process food in the direct electron mode, the throughput would be greater than 5000 M Rad Tons/day. It is not clear whether currently available conveyor systems could supply thin samples of food to the accelerator at a fast enough rate to utilize its tremendous throughput capability. A smaller induction linear accelerator with a reduced beam power of 0.1 MW would not be significantly lower in purchase cost than a 1 MW model. The advantage in using this type of accelerator at a reduced power mode arises from the ruggedness of the design and the reduction in variable costs of operation.

II. THE PROCESSING FACILITY

Central Processing Facility

The food shipments will be exposed to the radiation source at the processing facility before the food reaches the retail market.

The facility must handle both large volumes of food and an intense rediation source in a safe and economical manner.

A central processing facility consists of a fixed site where food shipments are received, processed and shipped out as rapidly as possible. A central facility will have to process better than 1000 tons of food daily therefore transportation and food handling will be major concerns.

The FDA will establish separate protocols for specific food types. This complicates the design of the central facility which must be flexible enough to accommodate each specific processing protocol.

A central facility design using radionuclide or electric sources will consist of an incoming shipping dock where boxes of food are unloaded onto a conveyor for transport into a well shielded source room. The food will remain on the conveyor during processing. The termination point of the conveyor will be at the outgoing shipping dock which should be separated from the incoming dock to prevent mixing processed and unprocessed food.

Portable Radiation Facilities

The small size and high power output of the induction linear accelerator makes the attractiveness of a truck mounted 5 MeV x-ray source a real possibility. A conceptual design of a portable source is shown in Figures 3 and 4. This source is the same design as shown in Figure 2 and should easily fit within a standard 48' trailer.

The food processing costs using portable sources of this type are estimated in the cost analysis section.

Radiation Shielding

During processing, the food will be exposed to dose rates of hundreds of rads per second while background exposures to nearby personnel must be kept below one rad per year. Source room radiation shielding equivalent to approximately 18 inches of lead must be used with 5 MeV x-ray machines. Five feet of concrete or ten feet of earth will be required while a nuclide source is in operation. Radionuclide sources will be stored underwater within a source room pool during non-processing periods.

A source shield must also be provided with nuclide sources for use during source replenishment and periods of pool drainage.

The small radiation volume required with 5 MeV x-ray sources of the design shown in Figure 2 makes the shielding of these sources feasible using lead plates. This allows the consideration of x-ray sources as processing tools to be implemented into existing food packaging lines thereby eliminating the need for a central processing facility.

Controls - Radionuclide Facility

The intensity of a radionuclide source depends upon the number of megacuries and type of source nuclide present. Food packages brought near the source will experience a higher dose rate but also a higher max/min dose ratio compared to packages processed at a further distance from the source. The use efficiency of the radiation declines as distance from the source increases because a smaller fraction of the radiation is intercepted by the processed package. It is possible to improve the max/min dose ratios at the higher dose rates close to the source by rotating the package one half turn and carrying it past the source for a second exposure.

The total dose applied to a given package partially depends both upon its distance from the source and the amount of time it is processed. The max/min dose ratio partially depends upon the

distance from the source. These variables can be controlled by adjusting both the speed and the track path of the conveyor system.

Controls - 5 MeV X-Ray Facility

The intensity of an x-ray source can be adjusted by varying the electric power delivered to the accelerator. The geometry of the radiation field can be adjusted with electric sweeping magnets so that most of the produced radiation is incident upon the package to be processed. Both of these adjustments have little effect upon the max/min dose ratio while preserving a high use efficiency. The max/min dose ratio can be enhanced if required by hardening the radiation at a penalty of reduced use efficiency.

Since the irradiation source characteristics can be modified to accommodate specific dose, dose rate, and max/min ratio, the conveyor system used with x-ray processing sources can be of a simpler design than conveyors used with radionuclide sources. The simple track path configuration using a one pass, straight through exposure shown in Figure 2 is sufficient for a great variety of processing protocols because of the flexibility inherent to the x-ray source.

Radiation Field Mapping

It will be necessary to periodically map the geometry and intensity of the radiation field by exposing radiation detectors placed at different locations within the source room. This must be done each time a radionuclide source is replenished because the field geometry and intensity are changed.

The radiation intensity and field geometry of an x-ray source are known functions of the electron voltage and current density. These parameters are monitored and controlled by the accelerator operator or by computer therefore field mapping will be required on a less frequent basis if electric sources are used. When mapping is required the smaller volume of the radiation zone will simplify the task.

Ventilation

Ozone gas is produced when ionizing radiation passes through oxygen in the atmosphere or in water. Therefore it will be necessary to ventilate the source room regardless of the type of radiation used.

It is possible that specific protocols may require irradiation processing in oxygen free or inert atmospheres to prevent the occurrence of undesirable radiochemical reactions. This procedure is easier to implement, as is ozone ventilation, when a small volume radiation zone is used.

III. COST ANALYSIS

Method

The operating expenses for a food processing facility were approximated by considering a central facility separately from the radiation source. These facility costs without the source are listed in Table 6. A source is then chosen to be fitted into the facility, and the source and facility costs are added to obtain the total operating costs. These costs are listed in Tables 7-10, one table for each of the four possible radiation sources chosen.

A figure of merit is defined as an average annual cost per M Rad Ton of food processed. This figure is not entirely satisfactory however, because it fails to take into account the variation in source characteristics and operating flexibilities discussed throughout this paper. Furthermore, the assumption that the source and facility costs can be calculated separately and

then added is accurate to a rough approximation only and neglects the ability to optimize the facility design to a specific source. Nevertheless, this analysis method does provide insight into the relative costs and limitations faced by the designer of an irradiation food processing facility.

A separate cost analysis was made for the portable facility illustrated in Figures 3 and 4. These costs are listed in Tables 11 and 12.

Central Facility Costs Without Source

The central facility is assumed to be similar to the facility described in Part II of this paper. It consists of a shielded and ventilated source room with a conveyor which carries food past the source at rates of several hundred tons per hour. The food is placed onto the conveyor at the receiving dock and removed at the loading dock where the conveyor terminates.

A radionuclide source must be submerged under approximately 15' of water when personnel enter the source room. A source pool designed to cover the source rack to a minimum depth of 15' would be about 20' deep, 12' long and 6' wide. The pool, together with a lift mechanism to raise and lower the source rack, would be an integral part of the source room. A water circulation pump and

chiller to remove energy dissipated in the core as well as required equipment.

If an electron source is used, then the source room can be significantly smaller and no pool is required. Instead, a small service shop and parts storage area is placed adjacent to the source room to facilitate routine maintenance.

The facility also includes a control room and Analytical Laboratory adjacent to the source room. The source operator has control over all aspects of the facility from within the control room. This includes source and conveyor operation and safety interlock reset capability.

The Analytical Laboratory includes radiation monitoring and detection equipment required to map the fields, calibrate dosimeters, determine dosimetry ratios, etc.

The initial capital cost of the facility without the source is estimated to be $1.2 million regardless of the source chosen. This assumption is clearly an approximation which is used only to provide a basis for a comparative economic analysis of the source choices.

It is assumed that the facility will be operated with an average annual uptime of 80% by a staff of five personnel. These include the two full time positions of Supervisor and Radiation Engineer

with annual salaries of $60,000 and $50,000 respectively. Three hourly employees operate the radiation source and load food. The accelerator operator is paid at the rate of $25/hr and the two tech-laborers are each paid $15/hr. An annual facility maintenance factor of $100,000 exclusive of the source was also allowed.

This analysis gives rise to an annual facility operating cost of $560,000 exclusive of the radiation source. The initial capital expenditure and annual operating costs for the facility without the radiation source are listed in Table 6.

Radionuclide Source Costs

The initial capital costs for a cesium or cobalt radionuclide source to process food at the rate of 100 @ 540 Tons/day within the central facility described above are listed in Tables 7 and 8. These costs consist of the source itself (see Tables 1 and 2), source delivery and setup within the facility, a source radiation shield, and the initial capital costs for the facility listed in Table 6.

Source delivery to the facility for initial installment and for source replacement must be made in separate shipments of 0.2 MCi each. This limitation is due to the size and weight of

available shielded radionuclide shipping containers and due to regulations imposed by the NRC and DOT.

A container rental charge of $1000 and a shipping charge of $3000 is typical within the industry for a 0.2 MCi delivery. These charges are listed in Tables 7 and 8 as a source delivery charge of $20,000 per MCi, but must be received in separate 0.2 MCi shipments.

The initial source set up charge of $100,000 and radiation shield cost of $500,000 are estimated for a 2.6 MCi cobalt-60 source. The same charges were also assumed for the 17.4 MCi cesium-137 source estimated in Table 7. The absence of commercial cesium processing facilities makes a more accurate estimate for cesium set up and shield costs difficult to obtain.

The annual operating costs for the radionuclide source result from the decay of the source and its replenishment. This includes the purchase and delivery of fresh radionuclide at a delivery charge of $4000 per 0.2 MCi or fraction thereof required.

A source replenishment charge of $30,000 is included to cover labor and expenses for installing source material into the source racks. This must be done annually with a cobalt source due to its fast decay rate. A cesium source can be replenished on a biannual schedule however, with less than a 5% loss in throughput. The

cesium operating expense in Table 7 assumes source replenishment once every two years however the annual average costs are listed.

The remainder of the operating costs consist of the non source related expenses of $560,000 to operate and maintain the facility listed in Table 6 and the payback of the initial capital investment which is assumed to be amortized at 15% annually over a 10 year period.

X-Ray And Electron Beam Source Costs

The initial costs specific to an electric central processing facility consist of the accelerator installation, spare parts inventory, and related equipment purchases together with the installation of the required electric utility capacity within the facility. The annual operating costs for x-ray processing are dominated by electric power charges. Both electron beam and x-ray processing require a 10% allowance for accelerator maintenance. The annual operating expense for both an x-ray and electron beam central processing facility are listed in Tables 9 and 10.

The x-ray facility is assumed to require twin 5 MeV electron accelerators capable of an average electron beam power totaling 1 MW. This power, when converted to x-rays, will process food at a rate of 346 M Rad Tons/day. These twin accelerators will cost

$900,000 as detailed in Table 5, and will require an input power of 2 MW. The facility will require a utility installation of 2.5 MW which requires an initial expense of $130,000 for a 13.8 kV substation, a 2500 kVA transformer and a 3 kA distribution panel.

An electron beam facility will require a 10 MeV electron accelerator which will produce a 0.1 MW electron beam. This accelerator is produced from the same components as the twin 5 MeV accelerators listed in Table 5, with the exception of the power supply which is only 0.1 MW. The lower power 10 MeV accelerator is assumed to cost the same as the twin 5 MeV accelerators since the number of required components is practically the same for both. The 0.1 MW, 10 MeV accelerator will require an input power of 0.2 MW and will process with electrons at a throughput of 519 M Rad Tons/day. We assume an 0.5 MW utility installation within the facility for an initial cost of $75,000.

Scanning magnets are used to shape the geometry of the x-ray and electron beam processing fields in order to maximize the use efficiency of both types of radiation. They serve to scan electrons across the converter plates or the food and focus most of the radiation upon the package regardless of package shape. Two magnetic scanners are required with the twin accelerators for x-ray processing. Only one magnetic scanner is needed with the electron processor.

The electric power charge, including fuel adjustment and demand charges, are based upon the assumed 80% uptime for the facility averaged annually.

The x-ray processor requires cooling water to remove heat from the converter plates. If the input temperature of the water is 60°F and the exit temperature is 160°F then 4.2 liters per second will be required while the twin accelerators are operating. This water has been cost factored at $1.50 per 1000 gallons. The water can be used for non processing purposes after it exits the converter plates if desired. If a cooling tower is utilized, then the water could be recirculated. The 10 MeV accelerator does not require water.

Central Facility Summary

The lowest processing cost per M Rad Ton was achieved with the electron beam facility due to its high use efficiency and low power requirements. This cost was $9.17 as shown in Table 10.

The 5 MeV x-ray facility processed food at a cost of $31.42 per M Rad Ton as listed in Table 9. This is equal to less than two tenths of a cent per pound processed to the 100 kRad limit proposed by the FDA. The x-ray facility is capable of significantly lower processing costs than either of the

radionuclide facilities (see Tables 7 and 8), primarily because of recent advances in accelerator technology.

Portable 5 MeV X-Ray Facility

The operating costs for the portable 5 MeV x-ray source and processing location shown in Figures 3 and 4 have been estimated and listed in Tables 11 and 12. It is assumed that an existing food packing facility can be retrofitted to accommodate the portable accelerators in the manner illustrated in the figures.

The portable twin 5 MeV accelerators will have a total length of approximately 35', including a two foot wide radiation zone for processing pallet sized containers. Each accelerator has a power output of 0.25 MW to produce a total electron beam power of 0.5 MW. This power is converted to 5 MeV x-rays to process at a throughput of 173 M Rad Tons/day. The only difference between these accelerators and the ones described earlier is the smaller power supply of 0.5 MW required for the portable source. This difference will produce only minor price variations and the total cost of $900,000 listed in Table 5 is used for this estimate.

Two scanning magnets, of the same type as described for the central facility, would increase the use efficiency of the

radiation as well as contribute to the flexibility of the radiation source.

The input power required to run the twin accelerator source is 1 MW which is provided by a van mounted, 1 MW diesel generator not shown in the illustrations. Under full load, the generator will burn fuel at a rate of 74 gallons per hour. Generators of this type are readily available and cost approximately $160,000.

The processing location requires construction to provide earth radiation shielding for the trailer mounted source and to provide conveyors for transporting food packages. It is estimated that 3200 cubic yards of earth must be excavated to provide the processing location and entrance and exit ramps for the trailer. This requirement could be reduced provided the truck could be backed into place.

A 5' thick concrete radiation barrier requiring 300 cubic yards is poured between the radiation source and the ground surface. If earth is used instead of concrete, then 10' would be needed thereby requiring a deeper excavation. The cut and cover operation is estimated to cost $100,000.

At least 10' of earth is required to protect personnel loading food onto conveyors. It is assumed that approximately 50' of conveyor will transport food as shown in Figure 4. Ventilation

will be required within the excavated volume to remove ozone from the area. This can be ventilated to the surface where the ozone disintegrates.

During full power operation, it is necessary to provide cooling water to the x-ray converter plates at a rate of approximately 0.6 gallons per second. The water will be increased in temperature by 100°F and can be used afterwards for other purposes.

We assume that the additional construction and retrofitting can be accomplished for $250,000. This cost is added to the cut and cover operation to produce a total estimated cost for the processing location of $350,000.

The total initial capital investment for both the portable x-ray source and the retrofit construction is just under $2 million. These initial costs are summarized in Table 11.

The operating expenses for the portable facility are listed in Table 12. It is assumed that the facility processes at a rate of 173 M Rad Tons/day with an average annual uptime of 80%. The net operating cost is $32.49 per M Rad Ton which is slightly higher than the operational cost of the central x-ray facility listed in Table 9. This difference is not significant.

The principal operating expense for the portable facility is the cost of the diesel fuel. Assuming $ 1.45 per gallon, the annual expense is $ 752,000.

Three personnel are necessary to operate the facility. They include two tech laborers, each at $ 15/hr and an accelerator operator who is paid $ 20/hr. These costs are included in Table 12.

A total maintenance allowance for the two accelerators and the diesel generator of $ 116,000 is estimated in Table 12. The payback of the initial capital investment at 15% amortized over a 10 year period is assumed in order to be consistent with estimates made throughout this paper.

Comparative Cost for Pest Control

A critical factor for implementing radiation processing of food for a certain intended effect, is the comparative cost with other methods. This is at best a difficult task because of the different requirements and cost factors. Based upon costs for several methods of pest control for raisins[8], the different radiation processing alternatives are cost compared. The radiation processing at 100 krad level assumes a throughput of 1000 ton/day when using radionuclide sources; 3460 ton/day (central facility) and 1730 ton/day (portable facility) when 5 MeV x-ray sources are used. This is compared with 800 ton loads per facility in non-radiation processes requiring several days. This comparison is given in Table 13.

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TABLE 1

PROPERTIES OF CESIUM-137

Gamma Photon Output	0.66 MeV
Output Power	3.32 kW / MCi
Cost	$100,000 / MCi
Decay Rate	2.28% per year
Max/Min Ratio (see text)	27 to 1
Approximate Use Efficiency	20%
World Supply	90 MCi of cesium chloride
100 M Rad Ton/day Requirement	17.4 MCi

TABLE 2

PROPERTIES OF COBALT-60

Gamma Photon Output	1.17 and 1.33 MeV
Output Power	14.84 kW / MCi
Cost	$1 Million / MCi
Decay Rate	12.39% per year
Max/Min Ratio (see text)	16 to 1
Approximate Use Efficiency	30%
World Supply	80 MCi
100 M Rad Ton/day Requirement	2.6 MCi

TABLE 3

PROPERTIES OF 5 MeV X-RAY SOURCE

X-Ray Photon Output	Broad spectrum to 5 MeV
Output Power	8% power conversion
Cost	Depends upon accelerator
Max/Min Ratio (see text)	5.9 to 1 or better
Approximate Use Efficiency	50%
100 M Rad Ton/day Requirement	0.29 MW, 5 MeV accelerator

TABLE 4

PROPERTIES OF 10 MeV ELECTRON BEAM

Electron Output	10 MeV
Output Power	Depends upon accelerator
Cost	Depends upon accelerator
Max/Min Ratio (see text)	Thin samples only
Approximate Use Efficiency	65%
100 M Rad Ton/day Requirement	0.0193 MW electron beam

TABLE 1

COST AND COMPONENTS FOR TWELVE ACCELERATORS 5 GeV 0.6mA PULSED
20% DF AND TWO/DAY THROUGHPUT

PRODUCTION LOGIC DESIGN

1 GW Power Supply	6 Mg Thousand
Resonant Charging Network	100
Switch Chassis (6 required)	200
Magnetic Switch (2 required)	200
0.5 GeV Accelerating Modules (20 required)	200
Magnet Power Supply (2 required)	20
Vacuum System	60
Controls	70
TOTAL	2850 Thousand

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[illegible]

[illegible]

TABLE 7

ESTIMATED EXPENSES FOR CERTAIN-TEED FOOD PROCESSING FACILITY
TEE @ BAD ROAD/IKE THOUSAND:T
BIN ANNUAL EFFORD

INITIAL CAPITAL INVESTMENT	
T1,0 BCl Source	$1,T0E,XXX
Delivery @ $15,XXX per BCl	1XE,XXX
Initial Source Setup	TXE,XXX
Source Modification Unicild	5XE,XXX
Central Facility - Table 6	T,5XE,XXX
TOTAL	$8,TBE,XXX
ANNUAL OPERATING EXPENSE	
Chemicals Decay (2.25%)	$ 2E,TXE
Replenishment Delivery (Average annual cost - three biannually)	8,XXE
Replenishment Labor and Expenses (Average annual cost - three biannually)	TT,XXE
Operating Expenses - Table 6	TXE,XXE
Capital Investment Payback at TIE, TE year amortization	$TT,XXE
TOTAL	$1,WTT,TXE
ANNUAL PRODUCTIVITY	2E,1XE # Bad Tires
OPERATING COSTS	$WE.5I / # Bad Tire

TABLE 8

OPERATING EXPENSES FOR COBALT-60 FOOD PROCESSING FACILITY
100 M RAD TONS/DAY THROUGHPUT
80% ANNUAL UPTIME

INITIAL CAPITAL INVESTMENT	
2.6 MCi Source	$2,600,000
Delivery @ $20,000 per MCi	52,000
Initial Source Setup	100,000
Source Radiation Shield	500,000
Control Facility - Table 6	1,500,000
TOTAL	$4,752,000
ANNUAL OPERATING EXPENSE	
Cobalt Decay (12.3%)	$ 322,000
Replenishment Delivery	8,000
Replenish Labor and Expense	30,000
Operating Expense - Table 6	560,000
Capital Investment Payback at 15%, 10 year amortization	946,000
TOTAL	$1,866,000
ANNUAL THROUGHPUT	29,200 M Rad Tons
OPERATING COSTS	$63.93 / M Rad Ton

TABLE 9

OPERATING EXPENSES FOR 5 MeV X-RAY FOOD PROCESSING FACILITY
346 M RAD TONS/DAY THROUGHPUT
80% ANNUAL UPTIME

INITIAL CAPITAL INVESTMENT	
Two 5 MeV, 0.5 MW accelerators	$ 900,000
Spare Parts	180,000
Two Scanning Magnets	250,000
2.5 MW Utility Installation	130,000
Central Facility - Table 6	1,500,000
TOTAL	$2,960,000
ANNUAL OPERATING EXPENSE	
Accelerator Maintenance 10%	$ 90,000
Electricity @ $0.135/kwh	1,890,000
Water @ $1.50 / 1000 gallons	43,000
Operating Expense - Table 6	560,000
Capital Investment Payback at 15%, 10 year amortization	590,000
TOTAL	$3,173,000
ANNUAL THROUGHPUT	101,000 M Rad Tons
OPERATING COSTS	$31.42 / M Rad Ton

TABLE 10

OPERATING EXPENSES FOR 10 MeV ELECTRON PROCESSING FACILITY
519 M RAD TONS/DAY THROUGHPUT
80% ANNUAL UPTIME

INITIAL CAPITAL INVESTMENT	
One 10 MeV, 0.1 MW accelerator	$ 900,000
Spare Parts	180,000
Scanning Magnet	125,000
0.5 MW Utility Installation	75,000
Central Facility - Table 6	1,500,000
TOTAL	$2,780,000
ANNUAL OPERATING EXPENSE	
Accelerator Maintenance 10%	$ 90,000
Electricity @ $0.135/kwh	190,000
Operating Expense - Table 6	560,000
Capital Investment Payback at 15%, 10 year amortization	554,000
TOTAL	$1,394,000

ANNUAL THROUGHPUT 152,000 M Rad Tons

OPERATING COSTS $9.17 / M Rad Ton

TABLE 11

INITIAL CAPITAL INVESTMENT FOR 5 MeV X-RAY
PORTABLE PROCESSING FACILITY
173 M RAD TONS/DAY THROUGHPUT

Portable Source	
Twin 5 MeV, 0.25 MW accelerators	$ 900,000
Spare Parts	180,000
Two Scanning Magnets	250,000
48' Tractor and Trailer	120,000
Diesel Generator - 1 MW in separate 48' trailer	160,000
Radiation Monitoring Equipment	15,000
Portable Source Subtotal	$1,625,000
Processing Location	
Excavation - 3200 cubic yards Concrete - 300 yards	$ 100,000
Construction Conveyors - 50 feet Ventilation Plumbing	250,000
Processing Location Subtotal	$ 350,000
INITIAL CAPITAL INVESTMENT	$1,975,000

TABLE 12

OPERATING EXPENSES FOR 5 MeV X-RAY PORTABLE FACILITY
173 M RAD TONS/DAY THROUGHPUT
80% ANNUAL UPTIME

Accelerator and Generator Maintenance	$ 116,000
Diesel Fuel; 74 gal/hr @ $1.45/gal	752,000
Water @ $1.50/1000 gal	27,000
Two Tech-Laborers @ $15/hr	210,000
Accelerator Operator @ $20/hr	140,000
Capital Investment Payback at 15%, 10 year amortization	394,000
TOTAL	$1,639,000

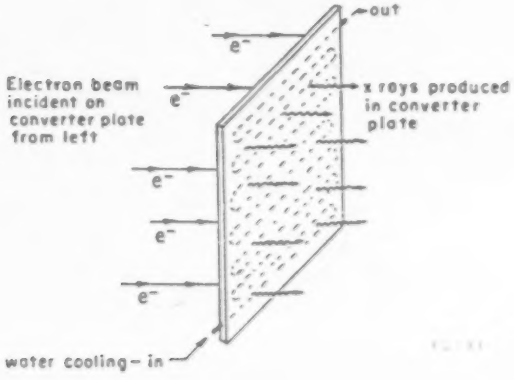
ANNUAL THROUGHPUT	50,516 M Rad Tons
OPERATING COSTS	$32.49 / M Rad Ton

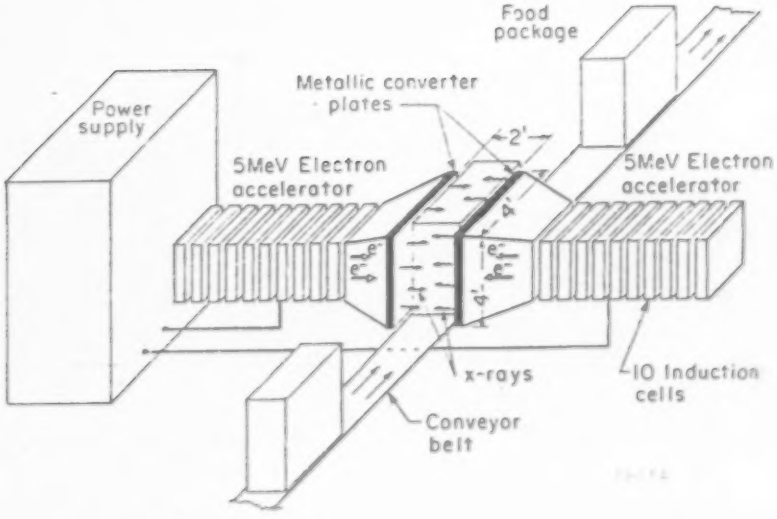
TABLE 13

COMPARATIVE PROCESSING COSTS FOR PEST CONTROL IN RAISINS

CURRENT PROCESS	COST PER METRIC TON
Methyl Bromide	$ 8.37
Phosphine	$ 10.75
Low-Oxygen Atmosphere	
(a) No heat recovery	$ 10.63
(b) 80% heat recovery	$ 9.77
(c) 90% heat recovery	$ 9.65
Nitrogen Atmosphere	
(a) Liquid nitrogen trucked in	$ 17.83
(b) Liquid nitrogen on-site production	$ 16.39
RADIATION PROCESS	
Cs-137 Facility	$ 4.99
Co-60 Facility	$ 6.39
5-MeV X Ray Facility	
(a) Central facility	$ 3.14
(b) Portable facility	$ 3.25

Bremsstrahlung Radiation





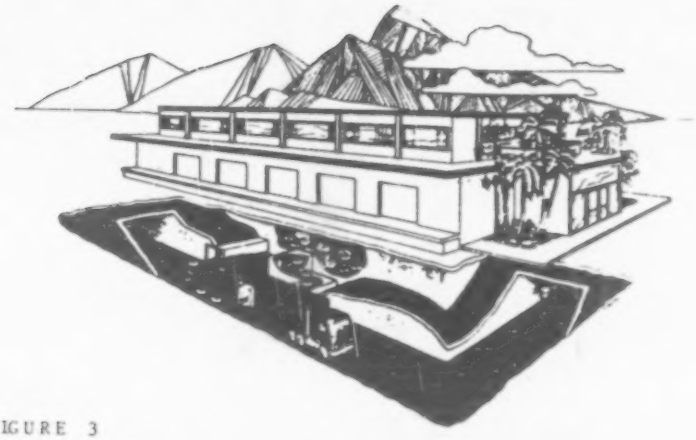


FIGURE 3

General view of an underground food irradiation facility using a portable two-sided 5-MeV electron accelerator.

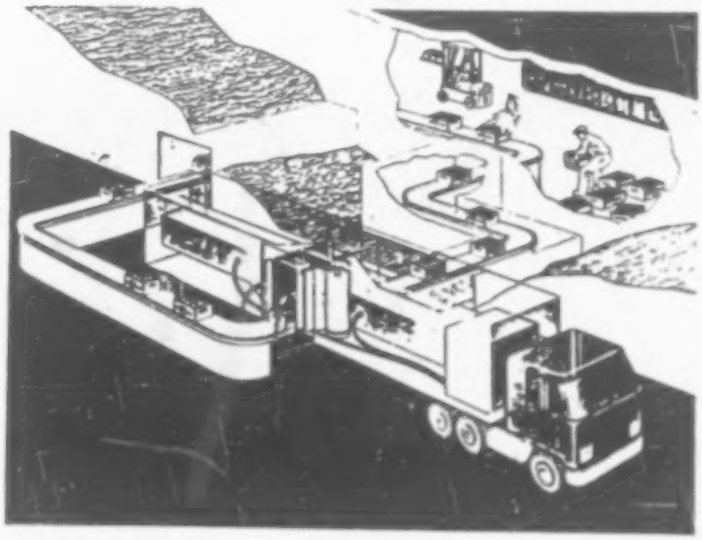


FIGURE 4

Close up view of a portable two-sided electron accelerator irradiating food. Facility uses soil and concrete as shielding.

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
INTERNATIONAL ATOMIC ENERGY AGENCY
INTERNATIONAL SYMPOSIUM ON FOOD IRRADIATION PROCESSING
March 4-8, 1985, Washington D.C., USA

DOSE RATIOS IN PALLET-SIZE FOOD PACKAGES AS A FUNCTION OF RADIATION SOURCES (*)

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The application of ionizing radiation in the processing of food depends largely on economic factors, as well as technical considerations (1). The ability to process large food containers with dose ratios as low as possible, is required in order to achieve and predict uniform responses. Many food products react negatively to treatments exceeding a certain dose level (2). Thus it is necessary to process these foods within specified dose levels to achieve the desired technical effect while at the same time complying with the mandated regulatory specifications. Because of economic restrains, it is highly desirable that this can be accomplished while treating large food packages. Pallet-size containers vary in overall dimensions but range from 60- to 90-cm thick, while food densities vary from 0.2 to 0.9 g/cm^3. If simple calculations of the photon flux at some distance away from the radiation source are carried out by using the familiar Lambert's law of exponential attenuation ($I = I_o e^{-\mu x}$), then results which are generally low are obtained with overestimated maximum/minimum dose ratios. This is due to the neglect of the contribution of secondary radiation. This secondary radiation consists of mostly of Compton-scattered photons with less energy than the primary radiation, and to a lesser extent by X rays resulting from photoelectric interactions followed by Auger electrons; annihilation radiation from the pair-production process; and bremsstrahlung from the slowing down of energetic electrons within the absorber. Because the net result of this phenomena is an increase in the total radiation energy deposited throughout the absorber, this increase is called "dose buildup", and depends on photon energy; physical characteristics of the absorber; and the geometry of radiation-source and food package (absorber). This buildup effect has already been suggested as an important factor in allowing the use of Co-60 as a source of radiation in the processing of pallet-size containers with acceptable dose ratios (3). However, it is expected that other machine sources of radiation (i.e. > 5-MeV X ray spectra from electron accelerators) will provide a more uniform dose distributions in these type of food containers (4).

A comparison of results obtained by solving a Boltzman transport equation for primary and secondary radiation in thick food packages, using area sources of Cs-137, Co-60, and X and electron radiation from several different energy (2 to 10 MeV) accelerators, will be given. The calculations will be compared to experimentally determined dose ratios for Co-60 and 2 MeV X radiation from a 2 MeV electron accelerator. These results will aid the evaluation of the potential of the different radiation sources for an economically acceptable large-scale radiation processing of food.

(*) Supported by University of California Nuclear Sciences Fund.

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IAEA-SM-272/83P
(Poster Presentation)

[illegible] IN [illegible]-GOSS FISH ENZYMES AS A FUNCTION OF [illegible] (*)

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ABSTRACT

Definite dye distributions in polyhedron envelopes of food were calculated with the DYEPOL dyeing theory applied on the 20-100 sequence of the heterocycle Lovenian Lovenian-Lovenian heterocycle. Each calculation required approximately 10 minutes of computer time.

THE DYES

The types of food were studied. The first type of food (food 1) was assumed to be 80% water by weight, with the remaining 20% evenly distributed between lipids, carbohydrates, and proteins. This type of food was assumed to be representative of fresh produce, and has an elemental chemical composition equal to $C_{1.0}H_{1.8}O_{0.9}N_{0.03}$. The second type of food (food 2) consisted of 20% water. Of the remaining weight, evenly distributed between lipids, carbohydrates, and proteins. Food 2 was representative of dried foods, and has a chemical chemical composition equal to $C_{1.0}H_{1.6}O_{0.6}N_{0.03}$. Although only two types of food were modeled, the food models can handle between 0 of and 1 grams.

METHODS

Multi-wise food samples of dimensions 0 x 0 x 0 in, which were used for dyeing calculations. Each food sample calculated was enclosed by an inner by a cardboard open dish was 0.125in. Wide and a density of 0.25 g/cm^3. The radiation source used for the calculations was either a radiographic source or a drug source. In all cases, the radiation source consisted of two flat panel source planes which were 0.5%, and 1.0% in each side. The two source planes were placed parallel to each other and separated by a distance slightly greater than 1 in, with the food package between them. Also, by 1.0%, which food sample was irradiated from both sides. The 1.0%, with dimension of the food sample was approximately placed into twenty equal parts in approximately each parallel to the source planes and 0.1 in. Wide by 0.1%, wide. Therefore, the resulting expected in each dose distribution when calculated and the calculated average dose were expected to each of the 20 food compartments. However, because of the symmetric shape and the simplicity, the figures only show each half of the right dose. Figure 1 shows this two-dimensional geometry model.

MONTE CARLO

When an x-ray source was used for dose distribution calculations, each photon was assumed to be a ray with 50 x-ray emission peaks. The ray tracking electron interaction begin starting at the inside surface of the 0% aluminum plate was positioned for each plate. The electron was assumed to impact the two planes at a right angle to the plate surface and the electron beam intensity was the monte carlo of each plate was assumed to be an uniform. The electron subscribers on the core plate surface caused x-rays to be emitted from the plate surface that was made to move down distribution calculations. The inner plane of the two electron spectrometers was assumed to be 0 - 90. From up to 0.2 MB of each plate. The energy of the electron beam was called between 1 MeV and 20 MeV, with ranging voltages for electron beam plate. An equation figure that was put a more efficient dose distribution were obtained with the higher energy electron beams.

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RESULTS

Table 1 summarizes the results of dose rate and dose distributions for a 2-ft. thick package filled with 0.75 g/cm^3 food , for filtered and unfiltered X radiation produced with 2-, 5-, 7-, and 10-MeV electron beams. These results are also shown in figure 2.

Figure 3 shows the effect on dose rate and particularly in dose distribution when some of the electrons are allowed to enter the food. It is quite clear that electron filters are necessary to obtain the lowest possible dose ratios, even at the expense of some of the photon power. These latter losses are shown in table 1 as a function of electron beam energy.

Table 2 summarizes the results of dose rate and dose distributions when radionuclide sources (Co-60 or Cs-137) are used to irradiate food of the exact composition and geometry as explained above. Figure 4 shows the comparison of these results for Co-60 and Cs-137 sources.

Table 3 is a comparison of dose rates and dose distributions for 0.75 g/cm^3 food as treated with the different radionuclide and accelerator sources.

Finally, Figure 5 shows the ideal case for anisotropic Co-60 and Cs-137 sources. In comparison to previously shown dose ratios for these sources, the calculated values (Co-60 1.19; Cs-137 1.45) reveals the importance and the effect of forward photon scattering in dose distributions.

CONCLUSIONS

Dose rates and dose distributions for two typical foods and over a range of food densities have been calculated for 1 MW X rays and 1 MCi radionuclide sources. These calculations show the following:

1) Electron accelerators provide photon radiation with lower max./min. dose ratios than either Co-60 or Cs-137 sources. This is due primarily to the forward scattering nature of accelerator-produced photon radiation. The higher energy of the accelerator-produced photons is also an important factor.

2) The food density is a significant factor in dose distributions. However, the food's elemental composition is not.

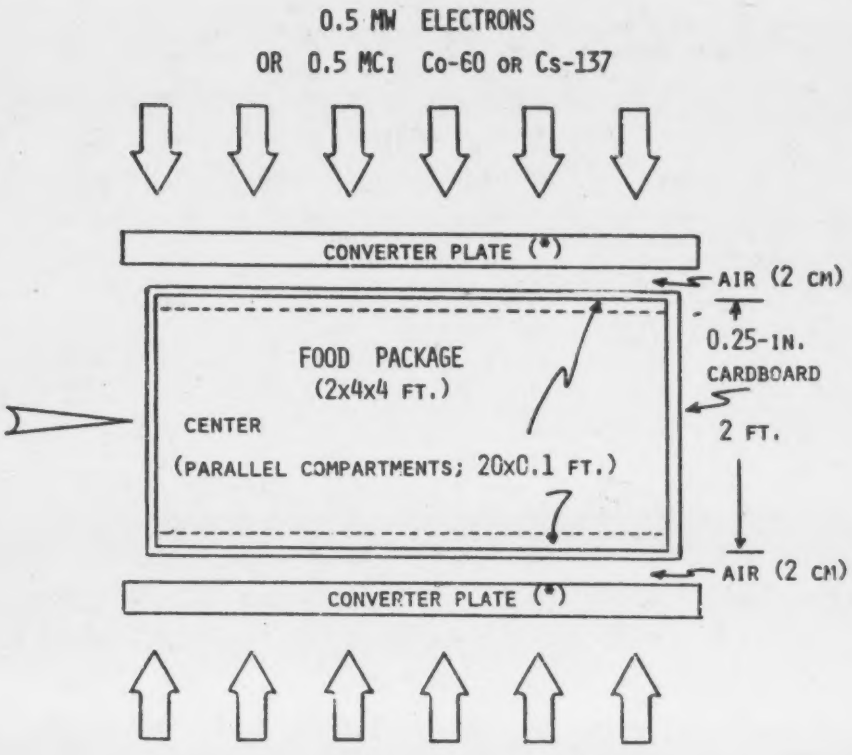
3) In addition to the primary photon beam, secondary scattered photons and electrons produced in the food must be included to determine energy deposition. Monte Carlo-type calculations are therefore, the appropriate method.

4) Converter plates that maximize X-ray production allow electrons to penetrate the plate. These electrons deposit their energy within the outer layers of the food raising considerably the dose ratios. Therefore, a low-Z electron absorber should be added to stop these electrons while still preventing large losses of photon radiation. Converter plate designs should be further investigated to maximize photon yields.

WORK IN PROGRESS

Other irradiation geometries, food packages, and photon spectra are being calculated using this method. The results will be reported in the scientific literature.

FIGURE 1. GEOMETRY OF RADIATION SOURCE/FOOD PACKAGE FOR SANDYL CODE CALCULATIONS.



(*) CONVERTER PLATE: Pb CONVERTER (1-MM)
WATER COOLING (2.6-MM)
Al (2.5-MM) AND 0.63-~~MM~~ CM Fe FILTER

TABLE 1. DOSE RATES, DOSE DISTRIBUTIONS, AND POWER LOSSES WITH FILTERED VS. UNFILTERED X RADIATION ON TWO-FEET THICK FOOD PACKAGES.

Food Density= 0.75 g/cm^3 ; Food Package= 2x4x4 ft.
Radiation Source= Parallel Plates; 0.5 MW electron beam/plate
Radiation Filter= 0.25-in. thick Fe

	ELECTRON BEAM ENERGY PRODUCING X RADIATION							
	2-MeV		5-MeV		7-MeV		10-MeV	
DISTANCE (*) (ft.)	Filter/No-Filter		Filter/No-Filter		Filter/No-Filter		Filter/No-Filter	
	Dose Rates (kRad/s)							
0.1	3.1	5.8	9.9	33.4	13.6	88.5	18.8	178.9
0.2	2.7	4.3	8.4	11.4	12.1	15.8	16.4	21.4
0.3	2.3	3.4	6.8	9.6	10.3	13.5	14.5	17.4
0.4	1.9	2.8	6.2	8.4	9.2	11.5	12.8	15.6
0.5	1.7	2.5	5.5	7.2	8.4	10.7	12.1	14.4
0.6	1.4	2.2	5.1	6.6	7.8	9.5	11.1	12.8
0.7	1.2	1.9	4.6	6.1	7.5	8.9	10.9	12.1
0.8	1.2	1.7	4.4	5.6	6.8	8.1	10.5	12.0
0.9	1.1	1.6	4.3	5.3	6.6	8.5	10.0	11.3
1.0	1.1	1.5	4.2	5.3	6.5	7.7	9.9	11.2
DOSE RATIOS	2.8	3.9	2.4	6.3	2.1	11.5	1.9	16.0
PHOTON POWER LOSS	27 %		21 %		16 %		12 %	

(*) Distance to each side of package from source plate

FIGURE 2. DOSE RATES, DOSE DISTRIBUTIONS WITH FILTERED X RADIATION ON TWO-FEET THICK FOOD PACKAGES.

(FOOD DENSITY 0.75 G/CM^3)

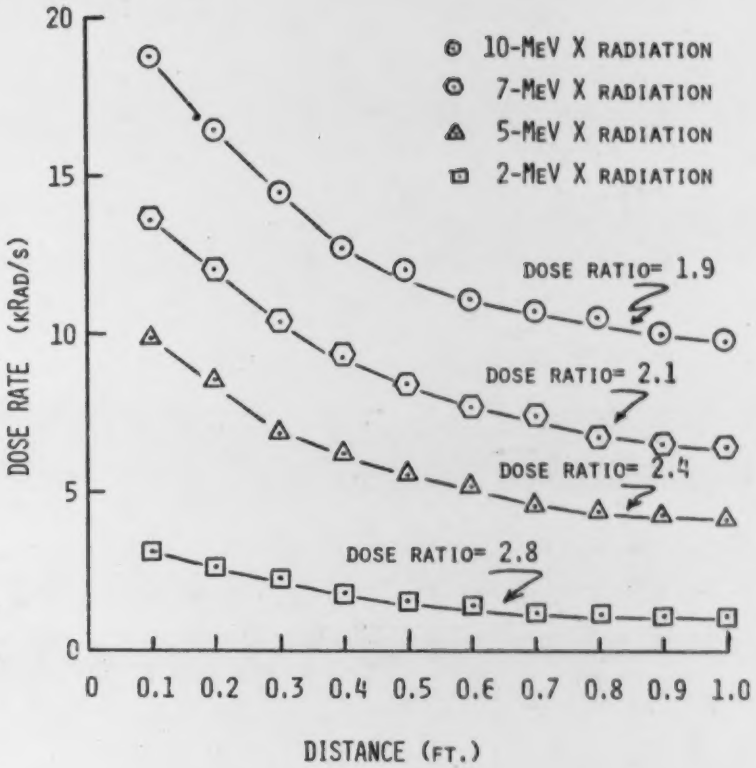


FIGURE 3. EFFECT OF FILTERED AND UNFILTERED X RADIATION FROM A 10-MeV ELECTRON ACCELERATOR ON 2-FT THICK FOOD. DOSE RATE AND DOSE DISTRIBUTION (FOOD DENSITY= 0.75 G/CM^3)

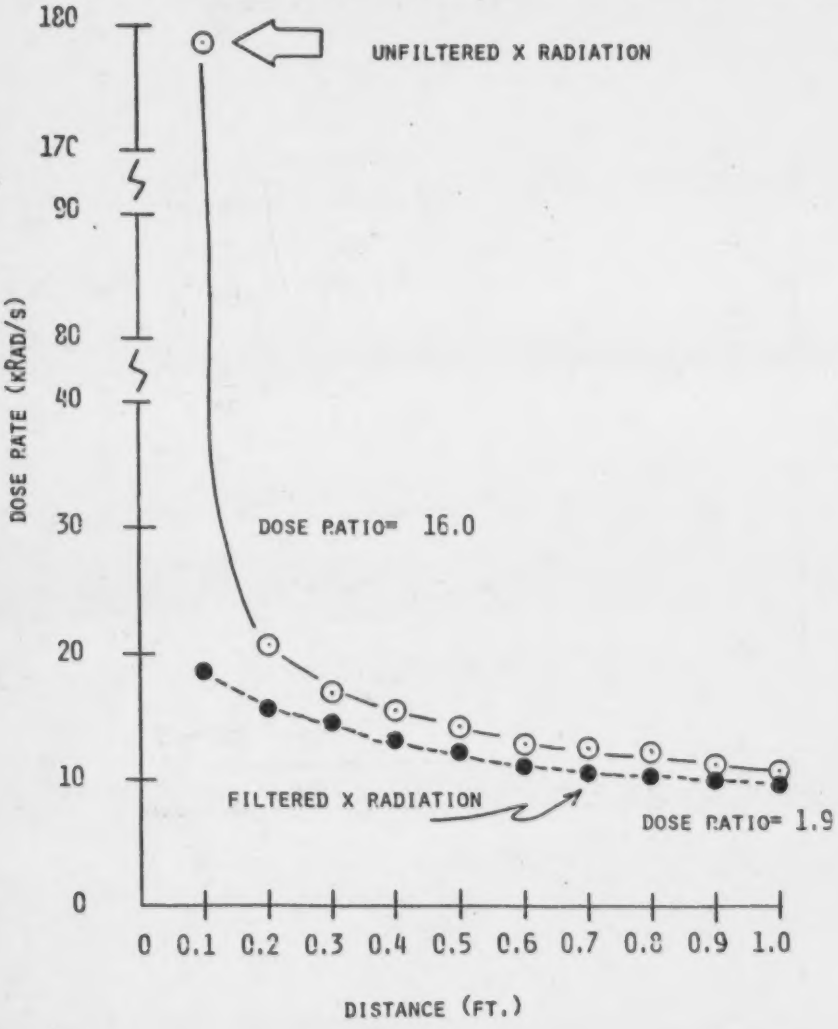


TABLE 2. DOSE RATES AND DOSE DISTRIBUTIONS FOR DIFFERENT FOOD DENSITIES FROM TWO-SIDED, PARALLEL-PLATE RADIONUCLIDE SOURCES.

DISTANCE (*) (ft.)	Co-60 (1)			Cs-137 (1)		
	Food Densities (g/cm^3)					
	0.5	0.75	1.0	0.5	0.75	1.0
	Dose Rates (kRad/s)					
0.1	0.67	0.63	0.60	0.37	0.35	0.33
0.2	0.50	0.43	0.39	0.28	0.24	0.21
0.3	0.40	0.34	0.28	0.22	0.18	0.15
0.4	0.34	0.27	0.22	0.18	0.14	0.11
0.5	0.30	0.23	0.18	0.16	0.12	0.088
0.6	0.27	0.19	0.15	0.14	0.10	0.071
0.7	0.25	0.18	0.13	0.13	0.085	0.058
0.8	0.23	0.16	0.11	0.12	0.078	0.051
0.9	0.22	0.15	0.10	0.12	0.069	0.044
1.0	0.21	0.14	0.098	0.11	0.068	0.043
DOSE RATIOS (MAX./MIN.)	3.2	4.5	6.1	3.4	5.1	7.7

(*) Food package 2x4x4 ft. Distance from each side of food package to source plate.
(1) Radionuclide sources has 0.5 MCi on each plate.

FIGURE 4. DOSE RATES AND DOSE DISTRIBUTIONS FOR DIFFERENT FOOD DENSITIES FROM 2-SIDED / PARALLEL PLATES RADIONUCLIDE SOURCES.

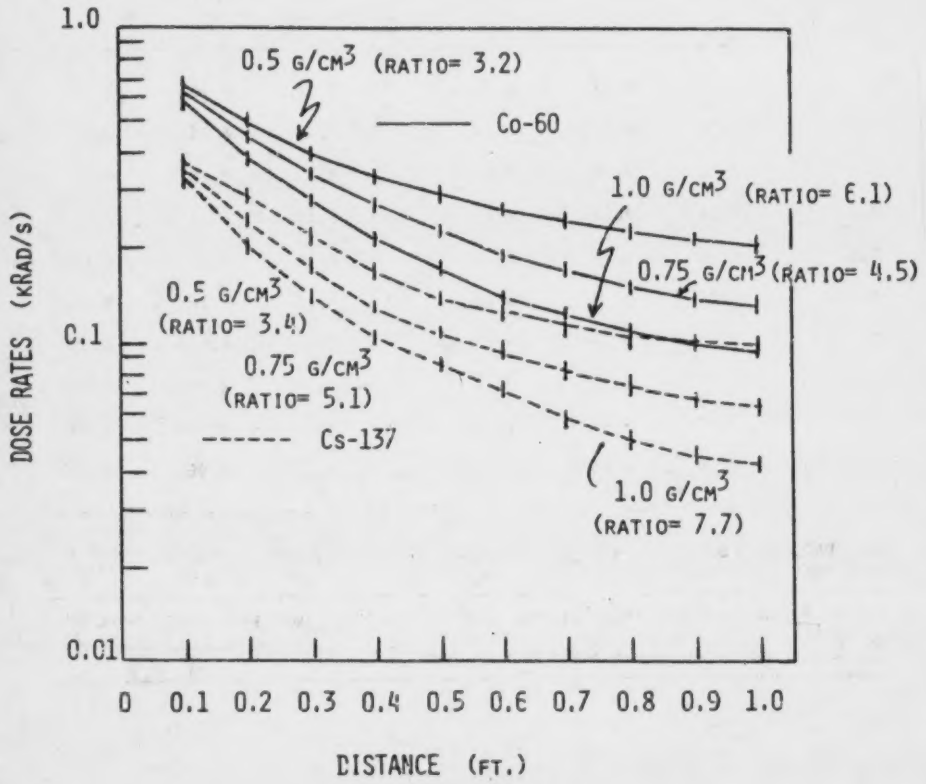


TABLE 3. DOSE RATES (kRad/s) AND DOSE DISTRIBUTIONS FOR DIFFERENT TWO-SIDED, PARALLEL PLATE RADIATION SOURCES.

(FOOD DENSITY 0.75 g/cm^3 ; FOOD PACKAGE 2x4x4 ft)

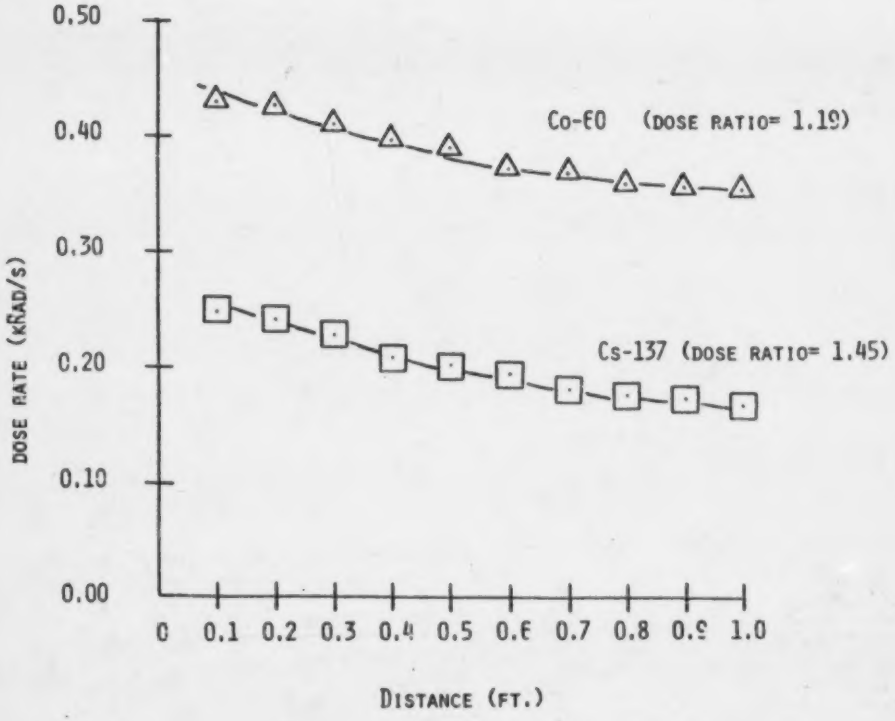
DISTANCE (*) (ft.)	RADIATION SOURCES					
	Radionuclide Sources (1)		Accelerator (X Ray) Sources (2)			
	Co-60	Cs-137	2-MeV	5-MeV	7-MeV	10-MeV
	Dose Rates (kRad/s)					
0.1	0.63	0.35	3.1	9.9	13.6	18.8
0.2	0.43	0.24	2.7	8.4	12.1	16.4
0.3	0.34	0.18	2.3	6.8	10.3	14.5
0.4	0.27	0.14	1.9	6.2	9.2	12.8
0.5	0.23	0.12	1.7	5.5	8.4	12.1
0.6	0.19	0.10	1.4	5.1	7.8	11.1
0.7	0.18	0.09	1.2	4.6	6.8	10.5
0.8	0.16	0.08	1.2	4.4	6.8	10.5
0.9	0.15	0.07	1.1	4.3	6.6	10.0
1.0	0.14	0.07	1.1	4.2	6.5	9.9
DOSE RATIOS (MAX./MIN.)	4.5	5.0	2.8	2.4	2.1	1.9

(*) Distance from each side of food package to the source plate.
(1) Radionuclide Source with 0.5 MCi on each plate.
(2) Accelerator 0.5-MW beam power on each plate (0.25-in. Fe filter).

FIGURE 5.

DOSE RATIOS WITH ANISOTROPIC RADIONUCLIDE SOURCES

(IDEALIZATION OF FORWARD SCATTERING EFFECT)



ACCEPTED FOR POSTER SESSION

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
INTERNATIONAL ATOMIC ENERGY AGENCY
INTERNATIONAL SYMPOSIUM ON FOOD IRRADIATION PROCESSING
March 4-8, 1985, Washington D.C., USA

SCIENTIFIC CONSIDERATIONS FOR THE USE OF 10-MEV X RADIATION IN FOOD PROCESSING(*)

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and (**) University of California Lawrence Livermore National Laboratory,
Livermore, CA. 94550, USA.

The recomendations of the Joint FAO/IAEA/WHO Expert Committee in 1980, on the Wholesomeness of Irradiated Food (1), limits the radiation sources to be used in radiation processing of food, to radionuclides (Co-60 and Cs-137) and machine sources generating up to 5-MeV X radiation and up to 10-MeV electron beams. This recommendation is generally being accepted throughout the world. However, there is no sciantific basis for excluding the use of up to 10-MeV X radiation converted from a 10-MeV electron accelerator, when at the same time the direct use of 10-MeV electron is permitted. The major factor into consideration for establishing the present recomendations is clearly the need to decrease the possibility of inducing radioactivity in food via photonuclear reactions. Becker (2) in 1983 reported that there is no theoretical or experimental evidence suggesting that induced radioactivity with up to 10-MeV electron beam energy is larger than 0.01% of the natural radicactivity content in food. However, food itself, its packaging, and to a much lesser extent the material adjacent to a 10-MeV electron accelerator facility, can act as electron-to-X ray converters, generating a broad spectrum of X rays (bremsstrahlung radiation) of up to 10 MeV. The direct electron-beam processing as presently defined will then be in violation with the intent of establishing the 5-MeV X-ray limit. The percent of the electron energy that is converted to X rays upon complete stopping of the electrons in a few materials is given by Brynjolfsson and Martin (3), and shown in table 1.

Table 1. Total X-ray production in percent of electron beam power for different materials as a function of electron energy

Electron Beam Energy-(MeV)	Materials	Percent of Electron Beam Power Converted to X Radiation
5.0	Water	2.00 %
	Al	4.00 %
	Fe	8.20 %
10.0	Water	4.16 %
	Al	7.72 %
	Fe	14.40 %

(*) Supported by the University of California Nuclear Sciences Fund.

As food is composed mostly of H, O, C, N, and other inorganic and organic elements, it is easy to realize that food itself and its package can provide several percent conversion to X radiation as seen in table 1. Bremsstrahlung production in several typical foods and packaging materials will be calculated in order to better evaluate the potential implications of increasing the X radiation limits. The use of machine sources with 10-MeV X radiation will also improve considerably the maximum/minimum depth dose ratios in large packages, while also making machine sources more efficient in the production of X rays.

REFERENCES

(1) "Wholesomeness of Irradiated Food". Report of the Joint FAO/IAEA/WHO Expert Committee. Technical Report Series 659, WHO, Geneva 1981.
(2) R. L. Becker. "Absence of Induced Radioactivity in Irradiated Foods". in Recent Advances in Food Irradiation, P. S. Elias and A. J. Cohen (Eds.) Elsevier Biomedical Press, 1983.
(3) A. Brynjolfsson and T. G. Martin III. Int. Journal Applied Radiation and Isotopes, 22, 29-40, 1971.

INTERNATIONAL ATOMIC ENERGY AGENCY
FOOD AND AGRICULTURE ORGANIZATION OF
THE UNITED NATIONS

INTERNATIONAL SYMPOSIUM ON FOOD IRRADIATION PROCESSING

Washington, D.C., United States of America, 4–8 March 1985

IAEA-SM-271/82p

SCIENTIFIC CONSIDERATIONS FOR THE USE OF 10-MeV X-RADIATION IN FOOD PROCESSING (*)

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(*) Supported by the University of California Nuclear Sciences Fund.

INTRODUCTION

The recomendations of the Joint FAO/IAEA/WHO Expert Committee in 1980, on the Wholesomeness of Irradiated Food (1), limits the radiation sources to radionuclides (Co-60 and Cs-137) and machine sources generating up to 5-MeV X radiation and up to 10-MeV electron beams. This recommendation is generally being accepted throughout the world. However, if the intent of the regulation is to prevent any photon with energy > 5 MeV to enter food, then the regulation is inconsistent.

There is no scientific basis for excluding the use of up to 10-MeV X radiation converted from a 10-MeV electron accelerator, when at the same time the direct use of 10-MeV electron is permitted. We believe that the major factor into consideration for establishing the present recomendations is clearly the need to decrease the possibility of inducing radioactivity in food via photonuclear reactions. However, there is no theoretical (and much less experimental) evidence suggesting that induced radioactivity with up to 10-MeV electron beam energy is larger than 0.01% of the natural radioactivity content in food (2).

THE USE OF "DIRECT" ELECTRONS IN FOOD

The notion that "direct" electron beams can be used to irradiate food is a misconception. Electron accelerators operate at very low vacuum requiring at the very least a thin, metallic isolation foil to separate the accelerating tubes from the atmosphere. When electron beams transverse this isolation foil, X radiation in the forward direction will also be generated (bremsstrahlung radiation). Electron beams are thus "contaminated" with a relative small fraction of X radiation. This fraction or its intensity, and the photon energy spectra (distribution) which reaches up to the electron energy (i.e. 10-MeV) are strongly dependent on the type of foil being utilized.

FOOD AS AN ELECTRON-TO-X RAY CONVERTER

Food itself, its packaging, and to a much lesser extent the material adjacent to a 10-MeV electron accelerator facility, can also act as electron-to-X ray converters, generating a broad spectrum of X rays (bremsstrahlung radiation) up to 10 MeV. Figure 1 shows the relative spectral distribution of X rays (photons) produced by a 10-MeV electron beam in matter. The magnitude of the shaded area corresponds to the fraction of photons with energies between 5- and 10-MeV. The fraction of > 5-MeV photons is dependent on the type of material being irradiated. In addition, table 1 summarizes and compares the total efficiency for converting electrons of 5-MeV and 10-MeV to x radiation (photons). As seen in this table every element can convert electrons to X radiation, although the efficiency of the process is highly dependent (increases) with the element's atomic weight.

Because of these simple physical facts, the "direct" electron-beam processing of food, as presently defined and interpreted seems to be in violation with the intent of establishing the 5-MeV X-ray limit.

OTHER CONSIDERATIONS

Dose rates (kRad/s) and dose distributions (max./min. dose ratios) are also important factors when considering the technical and economic needs for industry to be able to process large amounts of food. These two factors are being analyzed by these authors and a preliminary report is presented also in this meeting (see: "Dose Ratios in Pallet-Size Food Packages as a Function of Radiation Sources" IAEA-SM-271/83p).

Table 2 shows a summary of Monte Carlo type calculations performed for a 2-ft. thick food package (density= 0.75 g/cm^3) using X radiation generated with different energy electron beams. These results indicated a significant increase in product throughput capabilities as the electron beam energy increases. This is due to the ability to transfer more energy at the center of the package, which increases from 4.19 kRad/s at 5-MeV to 9.86 kRad/s at 10-MeV, for a 135% increase. Dose distributions within the 2-ft thick package are also significantly reduced with higher energy electron beams (dose ratio= 2.36 at 5 MeV; dose ratio= 1.90 at 10 MeV). Table 3 show both the dose rate and dose ratio variations for different food densities, and compares these factors when thes foods are treated with X radiation generated with 5- and 10-MeV electron beams. Food I is representative of fresh produce (~ 80% water) and Food II represents dried (10% water) food (see also IAEA-SM-271/83p).

The results shown in tables 2 and 3 demonstrates that a greater ability to control and predict the intended technical effects on irradiated food is better gained when 10-MeV X radiation is used. The economic impact of this needs not further comments.

COMPARISON WITH RADIONUCLIDE SOURCES

Finally, a comparison of dose rates and dose ratios when the same type of 2-ft. thick, 80% water (Food I type) food is irradiated with Co-60 or Cs-137 sources. When using these radionuclide sources, high dose rates will require multi-Megacurie of Co-60 or Cs-137 in a single facility. Furthermore, lower dose ratios will result in comparison to electron beam facilities.

WORK-IN-PROGRESS

Bremsstrahlung production in several typical foods and packaging materials, several other food/source geometries, and the potential for increased radioactivities in food are currently being evaluated. This information will be reported in the scientific literature.

TABLE 1. TOTAL X-RAY PRODUCTION (%) FOR DIFFERENT ELEMENTS RELATIVE TO 5-MeV AND 10-MeV ELECTRON BEAMS (*).

Element	Percent of Electron Beam Energy Converted to X Radiation	
	5-MeV Electron	10-MeV Electron
H	0.12 %	0.30 %
C	0.76 %	1.9 %
N	0.89 %	2.3 %
O	1.0 %	2.6 %
Na	1.4 %	3.7 %
Mg	1.6 %	4.1 %
Al	1.7 %	4.4 %
P	2.0 %	5.1 %
S	2.1 %	5.5 %
Cl	2.2 %	5.9 %
K	2.5 %	6.6 %
Ca	2.6 %	7.0 %
Fe	3.5 %	9.1 %
Zn	4.0 %	10.5 %
I	7.3 %	17.8 %

(*) From: "Tables and Graphs of Photon Interaction Cross Sections from 0.1 keV to 100-MeV derived from LLL Evaluated Nuclear Data Library" E.F. Plechaty et al., UCRL-50400 Vol.6 Rev. 3. Nov. 11, 1981.

TABLE 2. X RADIATION PROCESSING OF TWO-FEET THICK FOOD PACKAGES (FOOD DENSITY 0.75 g/cm^3). DOSE RATES (AT CENTER) AND DOSE RATIOS AS A FUNCTION OF ELECTRON BEAM ENERGIES (*)

Electron Beam Energy (MeV)	Dose Rate at Center (kRad/s)	Dose Ratio
2	1.14	2.72
5	4.19	2.36
7	6.55	2.08
10	9.86	1.90

(*) Two-sided, parallel-plate irradiation using 1-mm Pb converter and 0.5 MW of electrons on each side. Electron absorber 6.25-mm thick Fe.

TABLE 3. DOSE RATES AND DOSE DISTRIBUTIONS AS A FUNCTION OF FOOD DENSITY FOR 5-MeV and 10-MeV X RADIATION (*).

		Electron Beam Energy Producing X Radiation 5-MeV		10-MeV	
Food	Density (g/cm^3)	Dose Rate (kRad/s)	Dose Ratio	Dose Rate (kRad/s)	Dose Ratio
I	0.5	5.7	1.83	13.1	1.52
	0.75	4.2	2.4	9.9	1.90
	1.0	2.9	3.1	7.4	2.44
II	0.4	7.0	1.5	13.9	1.42
	0.6	5.1	2.1	11.5	1.66
	0.8	4.1	2.3	8.9	2.03

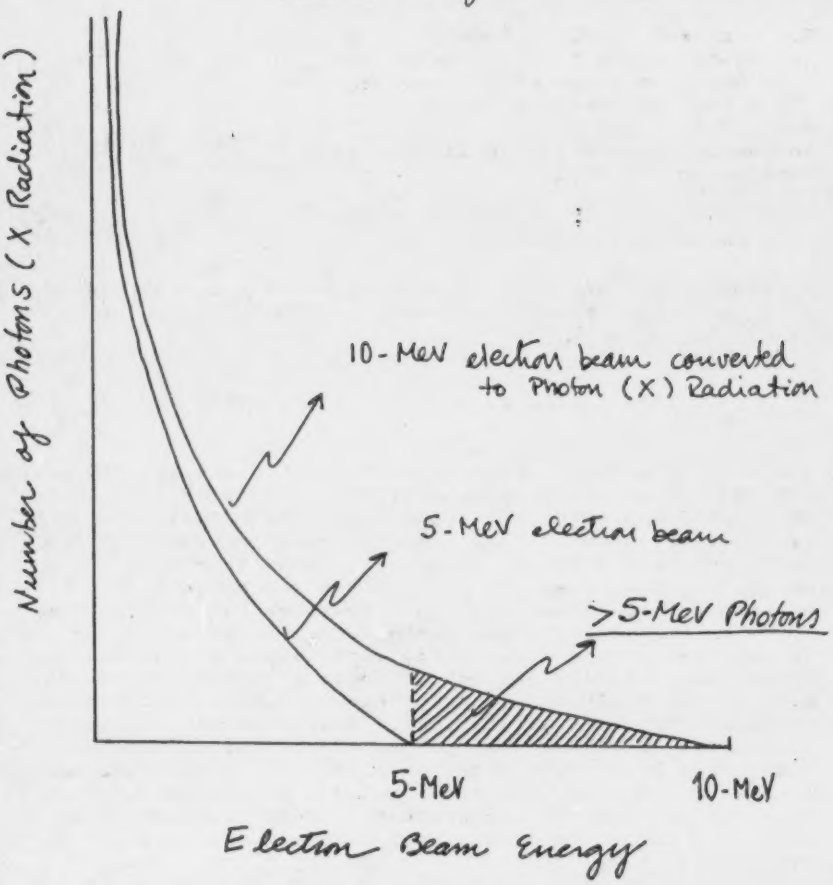
(*) Two-sided, parallel converter plates (1-mm Pb) with 0.5 MW electron beam power on each plate, filtered with 0.25-in. Fe.

TABLE 4. SINGLE-PLATE RADIONUCLIDE SOURCE IRRADIATION OF TWO-FEET THICK FOOD PACKAGES. DOSE RATES AT CENTER AND DOSE DISTRIBUTIONS (*)

Food Density (g/cm^3)	Radionuclide Source			
	1 MCi Co-60		1 MCi Cs-137	
	Dose Rate (kRad/s)	Dose Ratio	Dose Rate (kRad/s)	Dose Ratio
0.5	0.21	3.1	0.11	3.4
0.75	0.15	4.3	0.07	5.0
1.0	0.10	6.1	0.04	7.7

(*) Food composed of 80 % water, and equal parts of lipids, carbohydrates, and proteins.

FIGURE 1. Typical Photon Spectrum Energy Distribution for Different Electron Beam Energies.



Richard H. Conrad,
Ph.D.(Biochemistry)
950 Idylberry Road
San Rafael, CA. 94903
December 5, 1985

Attention: Tim Galvin, re: HR696

To: Chairman Berkeley Bedell
The House Agricultural Subcommittee
on Department Operations, Research,
and Foreign Agriculture
Room 1301
Longworth House Office Building
Washington, DC 20515

Dear Congressman Bedell:

I respectfully ask that my statement below be introduced into the public record in regard to HR696.

FOOD IRRADIATION IS NOT JUST ANOTHER PROCESS

Any way you look at irradiated food - texture, taste, amino acid analysis, electrophoresis, chromatography - it looks VERY DIFFERENT FROM RAW, COOKED, OR CANNED FOOD. Irradiation is definitely not just another process. The most important differences between irradiated and unirradiated food are many invisible and potentially dangerous biochemical changes. New chemical species are found in the fats, in the proteins and amino acids, in the carbohydrates, and most likely in a number of the hormone precursors normally present in foods. This is the first time in the 4,000,000 years of his evolution that man has regularly ingested catalytically active amounts of these compounds, which are commonly called URP's, or "Unique Radiolytic Products". The "U" might well also stand for Unknown or Unidentified or Untested. Do you want yourself, your family, and your constituents to be unwitting guinea pigs in a long-term experiment? What an enormous liability!

Recent history has supplied us with a very long list of "useful", "irreplacable", "wonderful", or "necessary" supposedly harmless compounds which have severely backfired, such as butter yellow, DES, thalidomide,

asbestos, birth control pills, DDT, and EDB. Will URP's be next? NO ONE can honestly say that they know. The very high energy of the irradiation produces many types of free radicals and also other unusual and highly reactive species which result in both volatile and non-volatile URP's, including the highly toxic benzene and toluene and other compounds never found in foods before. Their possible long-term cumulative effects include liver toxicity, allergic reactions, generalized changes in the immune system, carcinogenicity, and the potentiation of other carcinogens.

Virtually no studies have been done on the NON-VOLATILE URP's (mainly because they take more time and money to analyze than the volatiles), and there has been no research on possible IMMUNOLOGICAL EFFECTS IN HUMANS (consider the rapidly growing population of millions of people with multiple allergic sensitivities). The newly discovered significance of POTENTIATION OF NATURAL CARCINOGENS BY ARTIFICIAL COMPOUNDS has not been taken into consideration. What are the long-term effects of irradiated food on humans? If the government decides to concede to the wishes of the proponents of food irradiation, we may find out the hard way. The primary motivation of the proponents, who include few life scientists and a very large number of nuclear physicists, is not humanitarianism but the blind momentum of vested interest. Our history of errors is no comedy. It is inevitable that there will be other errors, but it is our job to do the best we can to prevent them.

There are a large number of very concerned citizens who want to see:

1) Full research BEFORE "testing" on the general population;

2) VERY CAREFUL EVALUATION of all research, which must take into consideration the credentials of the researcher, bearing in mind the unfortunate fact that a majority of scientific papers are biased towards what they want to prove rather than simply uncovering what nature has to tell us.

3) Active education of the public as to everything that is known AND UNKNOWN about food irradiation.

4) Acknowledgement that the burden of proof of dangerous side-effects lies not on the research laboratories or the consumer, but that it is the burden of PROOF OF SAFETY that is primary, and that this proof of safety is the

responsibility of the irradiators and the FDA;

5) FULL disclosure labeling of any food on the market that may contain even a small percentage of irradiated food.

Permitting irradiated or partially irradiated foods to be sold on the market or served in restaurants without full disclosure labeling would be a violation of our right to freedom of choice. TO FORCE CONSUMERS TO INVOLUNTARILY PARTICIPATE IN SUCH AN EXPERIMENT AS FOOD IRRADIATION WOULD CLEARLY BE UNCONSTITUTIONAL.

Sincerely,

Richard H. Conrad, Ph.D.

cc: Congresswoman Barbara Boxer, Senator Alan Cranston, and Denis Mosgofian

Sally Y. Conrad
Chittenden District

35 Wilson St.
Burlington, VT. 05401
658-1047

STATE OF VERMONT
SENATE CHAMBER
MONTPELIER
05602

The Honorable
Congressman Berkley Bedell
Chairman, Subcommittee on
Department Operations, Research
and Foreign Agriculture
House Agriculture Committee
Room 1301
Longworth House Office Building
Washington, D.C. 20515

November 22, 1985

Attn: Tim Galvin

Dear Congressman Bedell:

Please find enclosed the draft of a bill I intend to introduce in the January, 1986 session of our state legislature which would require labelling of irradiated foods coming into Vermont. This bill is an expression of my (and roughly 4000 constituents who signed a petition to that effect) strong objections to the proposals outlined in H.R.-696, which is before your committee for consideration.

From the research our staff attorney and I have done, I feel the scientific community is divided over the feasibility and safety of irradiation as a preservative. I believe the following problems exist: (1) creation of new chemical substances in foods, many of which have either been untested or inconclusively tested; (2) dilution of nutrients; (3) unkno n long-term health effects of eating irradiated foods; (4) numerous possiblities of environmentally hazardous spills from transporation of cesium-137 and cobalt-60 particularly in the case of proposed mobile irradiation units; (5) concern about eventual disposition of cobalt-60 and cesium-137 when they lose effectiveness as food irradiators, but still emit radioactivity.

First, I object to the food industry utilizing such a potentially hazardous process merely to extend shelf-life when our present preservation methods are perfectly suitable for the consumer. Second, I object to H.R.-696 in its entirety, but especially to the fact that the ACT will change current law so that labelling of irradiatred foods to inform the consumer will no longer be required by the Federal Food, Drug, and Cosmetic Act. As I recall, the United States Supreme Court has enumciated the right of consumers to receive relevant product information as a protectible interest encompassed by the First Amendment of the United States Constitution. •

Not Printed at State Expense

Congressman Bedell ... 2

Furthermore I believe consumer labelling should be clear, understandable and direct, without any attempt to disguise the fact that food has been treated by gamma or ionizing radiation.

I urge you and your committee to do all you can to defeat this legislation which is of utmost concern to me and my constituents.

I look forward to your reply.

Sincerely,

Sally Z. Conrad

Sally Z. Conrad
Senator
Chittenden District
State of Vermont

Enc.

* Virginia State Brd. of Pharmacy v. Virginia Citizens Consumer Council, Inc., 425 U.S. 748, 764-769, 96 S. Ct. 19817, 1826-1829, 48 L.Ed. 2nd 346 (1976)

cc: Brian Burgess, Deputy Attorney General, State of Vermont
Congressman James Jeffords
Senator Patrick Leahy
Senator Robert Stafford

(dr req 86-241 - draft 1) Page 1
10/21/85 (1.3)0177b

Introduced by Senator Conrad of Chittenden County

Referred to Committee on

Subject: Agriculture; food; irradiation; labeling

Statement of purpose: This bill proposes to require labeling of all irradiated foods which are sold or offered for sale in Vermont.

Own Vote			Legislative Vote					
Yes	No		Date	Senate	House	Yes	No	Date	Comments
		1st Reading							
		Com. Report							
		2nd Reading							
		3rd Reading							
		Amend.-Calendar							
		Amended-Journal							
		Amended-Journal							
		Committed							
		Recommitted							
		Ordered to Lie							
		Called up							
		Passed							
		Messaged							
		Com. of Conf.							
		Withdrawn							
		Sign.by Governor							

AN ACT TO REQUIRE LABELING OF ALL IRRADIATED FOODS SOLD IN VERMONT

It is hereby enacted by the General Assembly of the State of Vermont:

Sec. 1. 6 V.S.A. chapter 22 is added to read:

CHAPTER 22. IRRADIATION OF FOODS

§ 201. LABELING OF IRRADIATED FOODS

(a) Definitions. As used in this chapter, the following definitions shall apply:

(1) "Food" means fruits, vegetables, meats, poultry, eggs, dairy products and other natural and processed products offered for sale for human or animal consumption.

(2) "Irradiated food" means food treated with ionizing radiation from radioactive sources, x-rays, or electron beams and includes food containing a component which has been irradiated.

(b) Retail sales. All irradiated food sold in Vermont at retail shall bear, in addition to other information required by law, the following statements when applicable:

(1) "treated with ionizing radiation"; or

(2) "treated with gamma radiation".

(c) Wholesale sales. All irradiated food sold in Vermont at wholesale shall bear, in addition to other information required by law, the following statements on the products including the packaging and on invoices or bills of lading:

(1) "treated with ionizing radiation - do not irradiate again"; or

(2) "treated with gamma radiation - do not irradiate again".

(d) Method of labeling. The notice requirements of this section shall be satisfied by the following methods:

(1) labeling each irradiated food item individually and conspicuously; or

(2) posting a sign next to each display of an irradiated food item. The sign shall be at least 8" by 11" and the lettering, in contrasting color to the background of the sign, shall be at least one inch high. The sign shall state, "This food item (specific name), has been treated with either ionizing radiation or with gamma radiation."; or

(3) in the case of a restaurant or other food service establishment, placing an asterisk or other identifying mark beside the name of each irradiated food item where it appears on the menu, and by providing an explanation of the asterisk or other identifying mark at the bottom of each page of the menu on which an irradiated food is named. The explanation shall include the statement, "This food item has been treated with ionizing radiation or with gamma radiation."

(e) Penalty. Each day the provisions of this section are violated shall constitute a separate offense. Anyone found in violation of this section shall be fined not less than $5,000.00 nor more than $10,000.00 or imprisoned for not less than six months nor more than one year, or both.

Statement for hearing before the Department Operations Research and Foreign Agriculture Subcommittee of the House Agriculture Committee on bill HR 696 prepared by Lyn Dinelli on behalf of CARD--Citizens Against a Radioactive Dublin on November 14, 1985.

Understanding this hearing is concerned with opinions and statements regarding labeling irradiated foodstuffs I request you consider the total consequences of removing the requirement to label food. An example of what could happen in many cities across the country, if the D.O.E. has its way, is a thousand irradiation sites in the middle of populated areas. To clarify my point, here is what happened in Dublin, California.Local newspapers alerted the citizens of the city of Dublin in California of the possibility of a food irradiation facility in July 1985. Some ordinary citizens responded to the possibility of such a facility by gathering information and conducting a research project of food irradiation and irradiation facilities. What we learned caused us to form a community group called CARD or Citizens Against a Radioactive Dublin. We firmly and completely protest National Food Processors Association's intention to build this facility in our city. This project is probably better known to you as CACI--Commodities Agricultural Cesium Irradiator. A Department of Energy project. We protest the irresponsibility of both the DOE and NFPA for expecting us to accept a facility of this nature in the middle of our city. Redundant safety features and eight foot thick concrete walls would be necessary to contain three million curies of radioactive cesium 137. Within one quarter of a mile of the proposed site are hundreds of families, restaurants, small businesses, a high school, and a municipal sports field. The passage of this bill HR 696 would open the door for a thousand irradiation facilities to be built in the middle of many cities across our country. The passage of bill HR 696 would force the free citizens of the United States to live with the risk a large amount of radioactive material offers. We refuse that offer. We beg you to decide against this bill.

Thankyou,
Sincerely,

Lyn Dinelli

Lyn Dinelli
CARD(Citizens Against a Radioactive Dublin)
6979 Portage Rd.
Dublin Calif. 94568
415 8285263
November 14, 1985

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Congress of the United States
OFFICE OF TECHNOLOGY ASSESSMENT
WASHINGTON, DC 20510

JOHN H. GIBBONS
DIRECTOR

February 13, 1986

The Honorable Berkley Bedell
Chairman
Subcommittee on Department Operations,
Research, and Foreign Agriculture
Committee on Agriculture
U.S. House of Representatives
Washington, D.C. 20515

Dear Berk:

Enclosed is a copy of the study you requested in your letter of February 3, 1986. It is an OTA Contractor Document entitled Food Irradiation: New Perspectives on A Controversial Technology, A Review of Technical, Public Health, and Economic Considerations. It is the product of a year-long study conducted by Rosanna Mentzer Morrison and Tanya Roberts, economists with the Department's Economic Research Service, under an OTA-USDA cooperative agreement. This study was performed as part of OTA's ongoing Technology and the American Economic Transition Assessment.

This document does not necessarily reflect the analytical findings of OTA. However, in addition to internal reviews by OTA staff, this Contractor Document has been extensively reviewed by experts in the U.S. Department of Agriculture, the Food and Drug Administration, the Centers for Disease Control, and by personnel in many other institutions (please see "Acknowledgements").

We hope this document will be useful to your Subcommittee.

Sincerely,

John H. Gibbons

Enclosure

FOOD IRRADIATION: NEW PERSPECTIVES ON A CONTROVERSIAL TECHNOLOGY. A REVIEW OF TECHNICAL, PUBLIC HEALTH, AND ECONOMIC CONSIDERATIONS

Rosanna Mentzer Morrison
and
Tanya Roberts

Economic Research Service
U.S. Department of Agriculture

December 1985

"This Contractor Document was prepared by an outside contractor as an input to an ongoing OTA assessment. It does not necessarily reflect the analytical findings of OTA, the Advisory Panel, or the Technology Assessment Board."

Congress of the United States
Office of Technology Assessment

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EXECUTIVE SUMMARY

For many years, scientists have known that ionizing energy--radiant energy capable of breaking molecules into smaller, ionized or electrically-charged particles--can be used to sterilize or kill insects and microorganisms that cause food losses. The ionizing radiation kills the insect or microbial pest by damaging its genetic material and forming substances toxic to the organism. Irradiation also inhibits maturation in fresh fruits and vegetables. Irradiation is a "cold treatment" that achieves its effects without raising the temperature of the product significantly, thereby leaving the food closer to its unprocessed state.

Commercial use of food irradiation depends on many factors--its technical effects on food, the existence of demand for the benefits it provides, the cost of the technology and its competitiveness with alternative preservatives and fumigants, approval by regulatory authorities, and the willingness of consumers to buy irradiated food. This report addresses these issues by focusing on four feasibility criteria: technical feasibility, consumer acceptance and demand for benefits, economic feasibility, and regulatory approval. To provide a fuller context, the report also highlights international activities in food irradiation and major Federal research and development activities.

Stepwise Regulatory Approval

One important criterion governing the use of irradiation is regulatory approval. The Food and Drug Administration's (FDA) current thinking is to move in a stepwise fashion, approving general uses up to 100 krads (1 kGy) before considering the safety of medium and high dose applications. 1/ Low dose uses would include sprout inhibition, delay of ripening, sterilization of insects to satisfy quarantine requirements, and inactivation of parasites in meats. Extending approval to the 1,000-krad (10 kGy) maximum adopted by the Codex Alimentarius Commission would permit irradiation to be used for shelf life extension and public health purposes. The higher doses of 2,000 to 5,000 krads (20 to 50 kGy) needed to produce a sterile product have not been approved by FDA or any other governments.

Technical and Economic Feasibility

Regulatory approval is no guarantee that irradiation will be used. There are technical limitations of this process: undesirable changes in the food, the potential for reinfestation, the need for supplementary refrigeration in some cases, etc. Irradiating fresh produce can interfere

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1/ One rad equals 100 ergs of energy absorbed per gram of absorber. One thousand rads equal 1 krad. The International System of Units replaces the rad with the Gray (Gy). One kGy equals 100 krads.

On December 12, 1985, HHS Secretary Margaret Heckler signed a regulation permitting irradiation of fruits and vegetables at doses up to 100 krads (1 kGy). The regulation does not become a final rule until it is published in the Federal Register following review by the Office of Management and Budget.

with the product's normal metabolism and cause softening, increased sensitivity to chilling injury and rot, and uneven ripening. Protein foods, such as meats and poultry, have threshold dose levels above which off-flavors are produced. At the higher doses needed to sterilize meats and poultry, undesirable off-flavors and aromas are severe, requiring that the product be frozen when irradiated to reduce these changes.

The beginning point in answering the question of irradiation's economic feasibility is to determine the cost of the process. This information can then be compared with the value of the benefits irradiation may offer, as well as the cost of substitute processes, to make a judgement on its economic feasibility. The Economic Research Service decided to examine irradiation costs in terms of plant economies of scale. Economies of scale refer to the relationship between total average costs per unit of output (unit costs) and the size of the plant. Treatment costs for five food applications were estimated by Morrison for various sizes of cobalt-60 irradiators. Unit costs for the applications and volumes analyzed ranged from 8.5 to 0.2 cents per pound. Scale economies decrease as the size of the irradiator and the amount of product being treated increase. Plant economies of scale are pronounced for irradiators treating less than 30 million pounds per year, but become less important at annual volumes greater than 50 million pounds. Thus, an industry composed of fairly large firms would not have to fear that economies of scale for food irradiators would trigger rapid consolidation.

For irradiators treating less than 50 million pounds a year, size has a greater effect on average treatment costs. Food and agriculture firms that do not have the volumes to justify an in-house irradiator may have to join with other firms and build a free standing, centrally-located irradiator to treat their combined volumes. Smaller firms could also use the services of a contract irradiator who would charge a fee for the irradiation treatment.

For free standing and contract facilities, the cost of shipping the commodity to the irradiator is an added cost not included in this analysis. As free standing irradiators increase in size and production density remains constant, they will have to draw from larger geographic areas for their throughput. The transportation costs of moving the commodities to the larger irradiator may outweigh any gains in plant scale economies. This may bring the total cost of using a small irradiator more closely in line with that of a large facility.

Irradiation must compete with alternative food treatments both in terms of cost and acceptability to food safety regulators, processors, retailers, and consumers. If irradiation is being considered to replace an existing process that satisfies processors and consumers, it must demonstrate significant quality-enhancing properties or cost savings for a firm to abandon existing equipment and processing methods and build and operate an irradiator. In estimating the total cost of the irradiation treatment one must consider the costs of any disruptions to the marketing system. For example, as long as chemical sprout inhibitors applied in

the field are permitted to be used in the United States, it is unlikely that irradiation will be used for potatoes because of the costly extra handling step needed to bring them out of storage for the radiation treatment.

Another consideration is whether the irradiation treatment would introduce too long of a delay between harvest and retail for highly perishable commodities. Irradiation's economic feasibility would be strengthened if there is a consolidating point early in the marketing chain, so that additional transportation to the irradiator is not incurred. Along with large volumes, a desirable characteristic is steady, year round production--a quality not inherent to most fruits and vegetables.

Demand for Benefits

Irradiation's use on foods partially depends on the future of current alternative treatments. As more chemicals share the fate of ethylene dibromode (EDB), irradiation's future as a disinfestation treatment brightens. For uses where reinfestation is not important, such as in satisfying a quarantine requirement prior to export, irradiation may be appropriate.

Another potential benefit of irradiation is to lessen the incidence of some foodborne diseases associated with pork, chicken, and beef. Roberts estimated that the cost of medical treatment and lost productivity for five foodborne diseases--trichinosis, toxoplasmosis, salmonellosis, campylobacteriosis, and beef tapeworm--totals roughly one billion dollars annually. Trichinosis and beef tapeworm have relatively low estimated costs when compared to salmonellosis and campylobacteriosis (both intestinal diseases) and congenital toxoplasmosis (which can cause eye damage and mental retardation in fetuses). When potential benefits from irradiating chicken and pork are compared with estimated treatment costs, irradiation appears to have a favorable benefit to cost ratio of 2 or more. Other pathogen control options, however, may have higher net benefits than irradiation.

Radiation-sterilized meats in airtight cans or plastic pouches are likely to have a limited market in the United States because of established consumer preferences for traditional fresh and processed meats and high production costs. Irradiation costs are likely to be high because of the large dose, supplementary treatments needed to preserve quality, and protective packaging required. Radiation-sterilized meats may be demanded for specialty uses--submarines, space shuttles, camping trips--where space and weight are important considerations.

Consumer and Processor Acceptance

U.S. consumers' willingness to purchase irradiated foods is an important, and unknown, criterion. Consumers want to be confident that public regulators are adequately addressing safety and wholesomeness concerns. Also, an irradiated food's price must be competitive with its

non-irradiated counterpart or the benefits offered by irradiation sufficient to offset any price premium. Integral to consumer acceptance is retail labeling for those U.S. consumers who want to be informed and be able to choose or refuse irradiated food.

Food irradiation may grow slowly for a variety of reasons and will be used for applications where market conditions, such as industry structure, demand for its benefits, and value of the product, are conducive to the process. Irradiation's cost competitiveness with alternative treatments is another important factor affecting commercial development. The last chapter raises some of the important policy questions accompanying this technology in the areas of further safety testing, consumer education, worker safety, isotope availability, international trade, and other issues.

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I. INTRODUCTION

Food irradiation is receiving renewed attention by scientists, policy makers, agricultural producers, public health officials, and consumers. Interest in food irradiation's benefits and limitations has been piqued by recent concerns over the safety of chemical fumigants and preservatives and interest in reducing the incidence of foodborne diseases. Individuals concerned with food shortage problems in developing countries are eager to see if irradiation can be used to eliminate high spoilage losses in those countries. Food processors and retailers are always looking for less costly preservation methods and exploring new techniques to achieve desirable qualities in fresh and processed foods.

Food irradiation is not a new technology. British and American patents were awarded as early as 1905 to individuals who suggested that ionizing radiation could be used to preserve food (Josephson, 1983, p. 163). In 1943, scientists at the Massachusetts Institute of Technology demonstrated that ground beef could be preserved by exposure to X-rays (ibid, p. 164). Since that time, experiments on radiation's effects on food and safety tests have been conducted around the world. Irradiation is being used commercially on limited volumes of food in some countries to decontaminate spices and frozen fishery products, extend the shelf life of fruits and vegetables, disinfest grain, and a variety of other uses.

Today, in the United States, irradiation is legal for only a few foods. A rule proposed by the Food and Drug Administration (FDA) in February 1984 would open the regulatory door to wider usage on foods (49 FR 5714-5722). Low doses of radiation could be used to delay ripening of fresh fruits and vegetables and to kill insects that infest food.

Commercial use of food irradiation depends on many factors--its technical effects on food, the existence of demand for the benefits it provides, the cost of the technology and its competitiveness with alternative preservatives and fumigants, approval by regulatory authorities, and the willingness of consumers to buy irradiated food. This report begins to address these issues by focusing on four feasibility criteria: technical feasibility, consumer acceptance and demand for benefits, economic feasibility, and regulatory approval. To provide a fuller context, the report also highlights international activities in food irradiation and major Federal research and development activities.

The original analyses in this report are estimations of public health benefits and irradiation treatment costs. In chapter IV, Roberts develops monetary estimates of benefits in terms of medical costs, wages lost, and value of lives potentially saved from using irradiation to reduce Salmonella and Campylobacter contamination in fresh chicken, Trichinella and Toxoplasma gondii in pork, and Salmonella and tapeworm in beef. In the following chapter, Morrison presents estimates of irradiation treatment costs for five food applications. The focus of this research is the relationship between treatment costs and the size of the irradiator. The concluding chapter discusses important public policy issues raised by this technology.

Effects of Irradiation

Irradiation is a process where products are exposed to ionizing radiation to achieve a variety of effects. Ionizing radiation is radiant energy capable of breaking molecules into smaller ionized, or electrically-charged, particles. Irradiation has several industrial applications. One of the major uses in the United States is to sterilize disposable medical supplies. Irradiation is also used to treat the insulation on wire and cable, cross-link plastic food wrap, and cure scratch-resistent coatings on magnetic tape. In foods, the ionizing radiation can be used to sterilize or kill insects and microorganisms. The ionizing radiation kills the insect or microbial pest by damaging its genetic material and forming substances toxic to the organism. Irradiation also inhibits maturation in fresh fruits and vegetables. Irradiation is a "cold treatment" that achieves its effects without raising the temperature of the product significantly, thereby leaving the food closer to its unprocessed state.

The kinds of ionizing radiation used to treat foods are high energy gamma rays, X-rays, and electron beams. Gamma irradiation refers to the use of gamma rays emitted from the radioactive isotopes cobalt-60 and cesium-137. Electrons and X-rays are produced by an electron beam accelerator powered by electricity. Electrons have less penetrating power than gamma rays and X-rays, but they may be more economical for irradiating large amounts of small food particles. The energy levels of all three sources, used in accordance with FDA restrictions, will not make the food radioactive.

The effects of irradiation applied to a product depend on the absorbed dose, usually measured in kilorads (krad). 1/ At low doses of 5 to 100 krads (0.05 to 1 kGy), insects that infest grain and fresh fruits and vegetables are rendered unable to reproduce. In addition, this low dose range causes chemical and physiological changes that delay ripening of some fruits and sprouting in root crops, such as potatoes and onions. A low dose of radiation inactivates foodborne parasites, including trichinae, the organisms that cause the disease trichinosis in swine and humans.

Medium doses of 100 to 1,000 krads (1 to 10 kGy) reduce the number of spoilage microorganisms, thereby extending the shelf life of treated foods. This dose range also inhibits postharvest fungi development in fruits and reduces microorganisms that pose public health threats, such as salmonellae.

High absorbed doses of radiation from 2,300 to 5,700 krads (23 to 57 kGy) sterilize a food, and when combined with a mild heat treatment, the food can be stored in sealed containers at room temperature for many years. Heating kills foodborne viruses and inactivates enzymes in the food which would cause the food to decompose during storage.

The major problem with irradiating food is that often the dose needed to kill the insect or microbial pest causes undesirable changes in the treated food. Irradiating fresh produce can interfere with the product's normal metabolism and cause softening, increased sensitivity to chilling injury and rot, and uneven ripening. Protein foods, such as meats and poultry, have

---

1/ One rad equals 100 ergs of energy absorbed per gram of absorber. One thousand rads equal 1 krad. The International System of Units replaces the rad with the Gray (Gy). One kGy equals 100 krads.

threshold dose levels above which off-flavors are produced. At the higher doses needed to sterilize meats and poultry, undesirable off-flavors and aromas are severe, requiring that the product be frozen when irradiated to reduce these changes.

Feasibility Criteria

Four criteria will have an important role in the commercialization of food irradiation in the United States: technical feasibility, consumer acceptance of the process and demand for the benefits provided, economic feasibility, and regulatory approval. Chapters II through VIII discuss these criteria and irradiation's potential for meeting them.

Technical Feasibility

Not all foods are good candidates for radiation processing, just as not all foods are suitable for freezing or canning. Certain foods, such as dairy products, are more sensitive to the irradiation process and develop relatively strong off-flavors. Irradiation can cause softening and undesirable color change in fruits and vegetables. The exact effects of irradiation vary not only with the type of fruit or vegetable, but also with the variety, rainfall and fertilizer received, maturity at harvest, post-harvest handling, and other factors. Undesirable changes can be minimized by limiting the dose. This is also true for meat, poultry, and fish products. In many cases irradiation requires specific pre or post handling procedures.

Thus, the first step in determining the feasibility of irradiation is experimental work on the product's tolerance and compatibility with the irradiation treatment. Chapter II discusses some of these technical considerations.

Demand for Benefits and Consumer Acceptance

It is not enough that irradiation can meet various technical requirements as a method of food preservation. Processors, retailers, and consumers must desire these new attributes--extended shelf life, public health protection, or improved product quality--and be willing to bear any added cost of the treatment. An important consideration with processors and retailers is how well the irradiation treatment and the irradiated product fits into their current processing and handling procedures. Food companies are also interested in whether irradiation will allow them to make a desired change in current practices, such as shipping product by truck rather than air, packaging products more cheaply, or reaching currently unserved markets. Public health officials would like to see a reduction in the incidence of foodborne diseases and are interested in irradiation's potential in this area. Chapters II and III discuss in general terms some of irradiation's possible benefits. Chapter IV provides monetary estimates of health protection benefits from using irradiation to reduce foodborne diseases caused by fresh red meats and chicken.

As with any new technology, consumer acceptance is always uncertain. Processors and retailers are very concerned with how consumers will react to irradiated food. Food manufacturers may be unwilling to risk the good will

of their brand name by linking it with an irradiated product. Irradiated foods may have a greater than normal hurdle to overcome if people associate the process with radiation poisoning or nuclear accidents. Consumers must believe irradiated foods are safe if they are to knowingly eat them. Retail labeling of irradiated foods is linked with consumer acceptance. Chapter III discusses some of the safety concerns that have been expressed by scientists and consumers, and experiences with consumer acceptance of irradiated foods in other countries.

Economic Feasibility

In addition to technical feasibility and demand for the benefits, prospective users must believe that irradiation is economically feasible. Economic feasibility implies that the costs of the treatment are equal to, or preferably less than, the benefits. Irradiation must also compete with alternative treatments and achieve the same effect at a lower price or with fewer drawbacks (i.e., no harmful residues). Chapter V looks at irradiation costs in terms of plant economies of scale--the relationship between the cost of irradiating a food item and the size of the irradiator. Investment requirements and irradiation costs for cobalt-60 irradiators are estimated for a variety of applications. Chapter V also discusses how irradiation costs differ between free standing and integrated irradiators and the sensitivity of irradiation costs to increased cobalt-60 prices.

An alternative to gamma irradiation is to use machine-produced radiation like X-rays and high energy electrons. The benefits and limitations of these radiation sources in treating foods are discussed in chapter VI.

Regulatory Approval

Before irradiation can be used to treat food or feed, its use must be approved by FDA and, in the case of meat and poultry products, by USDA's Food Safety and Inspection Service. Currently, FDA has approved irradiation for wheat, wheat flour, white potatoes, spices, dried enzyme preparations, and pork. At present, only spices are being treated in the United States, and the volumes are small. One irradiation service company reports irradiating 20 tons of spices a week (Ransohoff, 1985). In 1984, FDA proposed new rules that would allow processors to irradiate a wider range of foods at doses up to 100 krads (1 kGy) and would raise the level of irradiation permissible for spices from 1,000 to 3,000 krads (10 to 30 kGy). The proposed rule would also establish additional requirements for persons irradiating food and change the existing labeling requirement. 2/

Chapter VIII discusses the regulatory environment for food irradiation, including FDA's proposed rule. The roles of the Nuclear Regulatory Commission, the Department of Transportation, and the Occupational Safety and Health Administration are also explained. In chapter IX, U.S. regulations are

2/ On December 12, 1985, HHS Secretary Margaret Heckler signed a regulation permitting irradiation of fruits and vegetables at doses up to 100 krads (1 kGy) and irradiation of herbs and spices at doses up to 3,000 krads (30 kGy) (Anon., 1985). The regulation does not become final rule until it is published in the Federal Register following review by the Office of Management and Budget.

contrasted with a proposed international standard for irradiated food and regulations in other countries using the process.

During the four decades of irradiation research and development, advances and refinement of other food technologies--aseptic processing, modified atmosphere packaging, CO_2 fumigation--have occurred. Chapter VII highlights some of the alternatives to irradiation in the areas of shelf life extension, public health protection, and improved product characteristics.

Chapter X describes major Federal research and development activities on food irradiation. The last chapter discusses the outlook for food irradiation and raises some of the important policy questions accompanying this technology in the areas of further safety testing, consumer education, worker safety, isotope availability, international trade, and other issues.

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II. TECHNICAL CONSIDERATIONS IN IRRADIATING FOODS

For many years, scientists have known that ionizing energy--radiant energy capable of breaking molecules into smaller ionized, or electrically-charged, particles--can be used to kill insect pests or destroy spoilage microorganisms that cause food losses. The ionizing radiation kills the insect or microbial pest by direct damage to its chromosomes and genes and by causing the formation of substances toxic to the organism. Irradiation is a "cold treatment" that achieves its effects without raising the temperature of the product significantly, thereby leaving the food closer to its unprocessed condition.

The effects of radiation depend on the amount absorbed, usually measured in kilorads (krads). 1/ At low doses of 5 to 100 krads (0.05 to 1 kGy), insect eggs and larvae are killed and adult insects are sterilized. Foodborne parasites are prevented from reproducing and maturing. This low dose range also causes chemical and physiological changes that delay ripening of some tropical fruits and inhibit sprouting in root crops. Medium doses of 100 to 1,000 krads (1 to 10 kGy) reduce the number of spoilage and pathogenic microorganisms that can contaminate foods. Very high doses of radiation in the range of 2,500 to 5,700 krads (25 to 57 kGy), in combination with heating, sterilize a food so it can be stored in sealed containers at room temperature for many years, free from the threat of botulism. Preheating is needed to kill foodborne viruses and to inactivate enzymes which would cause the food to decompose during storage.

One major problem with irradiating agricultural commodities is that often the dose needed to kill the insect or microbial pest causes undesirable changes in the exposed food. In the case of fresh produce, irradiation can interfere with the product's normal metabolism and cause softening, sensitivity to chilling injury and rot, and unwanted changes in appearance and organoleptic qualities. At the doses needed to sterilize meats and poultry, undesirable changes in flavor and aroma are produced, requiring that the meat and poultry be irradiated in the frozen state to reduce these effects.

Irradiation can also provide a measure of protection from public health hazards in foods. Many food poisoning bacteria, such as Salmonella and Campylobacter, are sensitive to medium dose radiation and their numbers could be significantly reduced. Bacterial spores would not be destroyed except at sterilization doses, and thus current control procedures would need to be maintained to control bacterial spore-formers such as Clostridium botulinum. Common parasites vary greatly in their susceptibility to radiation. Some parasites can be sterilized or rendered unable to infect humans at relatively low doses, but total parasite eradication can only be achieved at the 1,000 krad (10 kGy) level. Foodborne viruses are not affected by low to medium doses of radiation. Inactivation of viruses requires doses that are generally considered impractical for food irradiation (Urbain, 1984).

1/ One rad equals 100 ergs of energy absorbed per gram of absorber. One thousand rads equal 1 krad. The International System of Units replaces the rad with the Gray (Gy). One kGy equals 100 krads.

Problems also arise when irradiation is moved out of the highly controlled conditions of the laboratory and into field conditions. Radiation tends to damage, not improve, the quality of living cells. If the commodity to be irradiated is in less than prime condition, radiation may accentuate any flaws or cause other undesirable changes. Even for the same type of fruit, the exact effects of irradiation depend on variety, rainfall and fertilizer received, maturity at harvest, post harvest handling, and other factors. Often, irradiation must be done shortly after harvest or slaughter before the microbial load is too large. In the case of low and medium dose treatment of fish, poultry, and some fruits the irradiated product still requires refrigeration to realize an extended shelf life.

Irradiation kills insect and microbial pests only while the food is exposed to the radiation. There are no "residues" to ward against reinfestation and recontamination. Unless protective measures are taken, such as adequate packaging, irradiated food can be reinfested.

The following sections discuss some of the technical considerations and limitations of different applications of radiation in preserving foods.

Inhibit Sprouting of Root Crops

One commonly cited use of ionizing radiation is to control sprouting of root crops like potatoes, onions, and garlic. Irradiation inhibits sprouting at very low absorbed doses of 5 to 15 krads (0.05 to 0.15 kGy) with little effect on firmness. Radiation's ability to prevent sprouting is associated with inhibition of cell division and with elongation at growing points; the result is deformed buds that can not grow. Radiation's effect on cell division, however, also reduces the ability of potatoes and other tubers to heal cuts and bruises received during harvest. Rot-causing organisms can enter through these cuts and cause decay. Therefore, researchers recommend that potatoes be irradiated after a sufficient curing time and at doses below 15 krads to avoid interfering with the healing process (Matsuyama and Umeda, 1983, p. 182).

A time delay between harvest and irradiation is also needed to avoid browning of the raw potato. Browning can be reduced by waiting 1 to 2 months after harvest or by low temperature storage at 5° to 7°C (41° to 45°F) after irradiation (Matsuyama and Umeda, 1983, p. 184). Waiting for potatoes to cure before irradiation means that they would have to be rehandled after entering storage.

Browning of irradiated potatoes during cooking or processing is a problem for certain varieties and growing conditions. Matsuyama and Umeda list several methods to prevent or reduce discoloration such as temperature control, prepeeling, or soaking and cooking in citric acid solution (p. 187). If these procedures add an additional step to current processing practices, this cost or inconvenience must be recognized.

Irradiated onions display a darkening of inner buds, but it is not a serious problem for marketing value (Matsuyama and Umeda, 1983, p. 188). This darkening may not be acceptable for dehydrated onions. However, storage at 3° to 5°C (37.4° to 41°F) has been found to prevent bud darkening (ibid, p. 189). Sprout-inhibiting doses of radiation do not prevent storage rot in onions (ibid, p. 183).

In the United States, chemicals such as maleic hydrazide and chloroisopropyl carbamate are used to inhibit sprouting of potatoes and onions (Kader et. al., 1984, p. 2).

Disinfest Stored Grain

Grain disinfestation is often talked about as one of the "low-dose" (less than 100 krads) applications of radiation. This is true if the objective is to prevent insect eggs from hatching or to sterilize insect invaders. If a complete kill is desired, a medium dose of 100 to 200 krads (1 to 2 kGy) or more would be needed (Tilton and Burdit, 1983, p. 220). A sterilized insect will not produce offspring, but it will continue feeding and damage the grain. However, researchers have found that irradiated insects feed at reduced rates (ibid, p. 223).

Determining the appropriate dose of radiation to apply to the grain is complex. As Tilton and Burditt point out, the large number of insect species that may be present means that an effective dose must control (either kill or sterilize) the most resistent of the species present. This is further complicated by the fact that the sensitivity of any species to radiation can be affected by many factors including the insect's stage of development (egg, larva, pupa or adult), its sex, the food host, temperature, and type of radiation (Tilton and Burditt, 1983, p. 218). A recent Council for Agricultural Science and Technology (CAST) report concludes that if commodities are infested with many different insects, a 50 krad (0.5 kGy) dose will control even the most resistent beetle species and immature moths. Some adult moths might remain fertile, but their few offspring would be sterile because of inherited genetic damage (Tilton and Nelson, 1984, p. 3).

Researchers have also looked at the possibilities of lowering the amount of ionizing radiation needed by combining it with other treatments. Heating, infrared radiation, and microwave radiation each has a synergistic effect with gamma radiation. Other tests were made to determine if ionizing radiation is compatible with chemical control methods. Red flour beetles were found to be slightly more susceptible to malathion (a commonly used grain protectant) after they were irradiated with a dose of 10 krads (0.10 kGy) or more (Tilton and Burditt, 1983, p. 222). Experiments combining fumigation with methyl bromide and gamma radiation did not clearly demonstrate that the joint effect of the two treatments was greater than the sum of each treatment applied singly (Tilton and Nelson, 1984, p. 3). Irradiation under an atmosphere of nitrogen, carbon dioxide, or helium, or under a partial vacuum decreases an insect's sensitivity to the radiation (ibid).

Much of the current interest in irradiation has centered around its possible use as an alternative to chemical fumigants such as ethylene dibromide (EDB) to kill insects that infest stored grains and nuts. Irradiation can offer some measure of insect control without the dangers of carcinogenic residues. However, this lack of residual fumigant also means that reinfestation can be a problem as soon as the grain or nuts leave the irradiation chamber if preventive measures are not taken. One option would be to irradiate grain and nuts in bags that would provide a barrier against insects.

II-4

Disinfest Fresh Fruits and Vegetables

As with irradiation of potatoes and other root crops, disinfestation of fresh fruits and vegetables involves applying radiation to a living product. The amount of radiation needed to kill an adult insect may, in many instances, severely damage the fruit or vegetable host. If, however, the objective is changed to controlling insect pests by stopping reproduction, a dose of 5 to 75 krads (0.05 to 0.75 kGy) would be sufficient. At this level, some developmental stage of insects may survive and damage the product and even evolve into adults. However, the adults will be sterile, or in the case of some moths, their offspring will be sterile (Kader et. al., 1984, p. 2).

In addition to avoiding loss from insect feeding, disinfestation is also an important step in meeting quarantine restrictions designed to avoid the accidental introduction or spreading of plant pests from the exporting to importing country.

Burditt states that "fruit flies of the family Tephritidae are among the most important pests to be considered in developing quarantine treatments" (Burditt, 1982, p. 57). Irradiating fresh produce at an absorbed dose of 25 krads (0.25 kGy) has been suggested as an effective quarantine treatment against fruit flies (Kader et. al., 1984, p. 2). The 25-krad dose would prevent emergence of viable adults from eggs or larvae. Adults that might emerge from irradiated pupae would be sterile (Tilton and Burditt, 1983, p. 223). This assurance of sterility rather than complete kill would require a change in current U.S. quarantine regulations which require that a treatment result in at least 99.9968% mortality, or less than 1 survivor out of 31,250 (Burditt, 1982, p. 51). Cox points out another consideration,

> "Although desirable, complete kill of the fruit flies in fruit and vegetables is not absolutely necessary. However, there must be no possibility that adult flies, even if sterile, will emerge from fruit that reaches the mainland. Otherwise, mainland authorities might have to institute an unnecessary, expensive eradication program, inasmuch as differentiation between the sterile and normal flies is often impossible" (Cox, 1971, p. 24).

In a 1985 report to Congress, USDA suggested that the inability of radiation-treated adults to fly would be an acceptable criterion to distinguish between treated and untreated insects (Secretary of Agriculture, 1985, p. 11). This report also says that research is sufficient to prescribe a papaya irradiation quarantine treatment of a minimum of 15 krads (0.15 kGy) absorbed by the insect larvae (ibid, p. 9).

Problems of dose levels and intolerance arise when irradiation is moved out of the laboratory to a commercial situation where fruits and vegetables might be irradiated in crates or pallets. A recent CAST publication points out the pitfalls of working with pallet and bulk bin loads. "Estimates indicate that a dose of about 0.5 kGy (50 krad) is needed on the outside of such units to achieve a dose of 0.3 kGy (30 krad) in the center. Since a dose error of 20% must be considered, some outside fruits may be exposed to 0.6 kGy (60 krad)" (Kader et. al., 1984, p. 3). More research is needed to design the proper protocols. Better movement configuration or working with smaller

units may avoid this "overdose" situation. More sophisticated irradiator designs with more even radiation fields may overcome this problem.

Extend Shelf Life of Fresh Produce 2/

Another proposed use of ionizing radiation is to extend the shelf life of fresh fruits and vegetables. Shelf life can be extended in three ways: delay of ripening, delay of senescence (aging), and control of decay organisms such as molds, if present on the commodity. However, not all fresh fruits and vegetables are successful candidates for irradiation treatment. In many instances, the dose needed to extend shelf life causes undesirable changes in texture, appearance (mottling), or other organoleptic qualities. The major limitation to using irradiation for this purpose is textural changes (Maxie and Sommer, 1968, p. 39). Irradiated fruit often becomes soft and subject to injury during transit. For chilling-sensitive fruit, such as bananas and tomatoes, researchers found that irradiation significantly increases the sensitivity of the fruit to low temperatures (Maxie, et al., 1971, p. 99).

Delay of postharvest ripening can only occur in commodities which ripen normally after harvest such as bananas and pears. The doses needed to delay ripening vary from fruit to fruit. For tropical fruits like sapodillas, guavas, and bananas, doses of 10, 30, and 40 krads (0.1, 0.3, 0.4 kGy), respectively, have added from 3 to 9 days to their room temperature storage times (Sreenivasan, et al., 1971, p. 75). Irradiation has also been found to inhibit ripening of papayas and mangoes. In comparison, 100 to 300-krad (1 to 3 kGy) doses delay the ripening of pears, but upon ripening, they were mealy and tasteless (Akamine and Moy, 1983, p. 131). In the cases of peaches and nectarines, irradiation accelerates the ripening process (ibid, p. 150).

Delay of senescence, or aging, by irradiation has been demonstrated for sweet cherries, apricots, and papayas (Akamine and Moy, 1983, p. 150).

Radiation may be used to control postharvest fungi if the fungi are more sensitive to radiation than the host commodity. Often success depends on the particular fungus, its stage of growth, and the level of infection. A recent CAST report points out that while 175 krads (1.75 kGy) is the minimum dose required for effective inhibition of postharvest fungi (many molds require 200 krads), 225 krads (2.25 kGy) is near the maximum dose that most fresh commodities can tolerate (Kader et al., 1984, p.4). This implies a 1 to 1.28 minimum to maximum dosage ratio which may not be achievable under commercial conditions. In a recent review of irradiation studies on 27 fruits, irradiation could be used to control storage decay (without damaging the fruit) only for tomatoes, strawberries, and figs (Akamine and Moy, 1983,

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2/ In this section, we move into applications that involve a medium dose of ionizing radiation (100 to 1,000 krad or 1 to 10 kGy). The U.S. Food and Drug Administration is currently considering expanding the list of foods that can be irradiated, but only up to a maximum dose of 100 krad (except for spices). The Codex Alimentarius Commission, an international group that develops global food standards, recommends an average dose of 1,000 krads as safe for use on foods. The sterilizing doses discussed at the end of the next section are 2 to 6 times greater than the Codex level.

p. 150). Questions remain about uneven ripening and softening of tomatoes. In the case of strawberries, the radiation treatment must be accompanied by refrigeration.

In their review of 27 fruits (including fruit vegetables such as tomatoes, cucumbers, etc.) Akamine and Moy determined that only bananas, mangoes, papayas, sweet cherries, apricots, tomatoes, strawberries, and figs may achieve extended shelf life through irradiation treatment (figure 1). However, generalizations

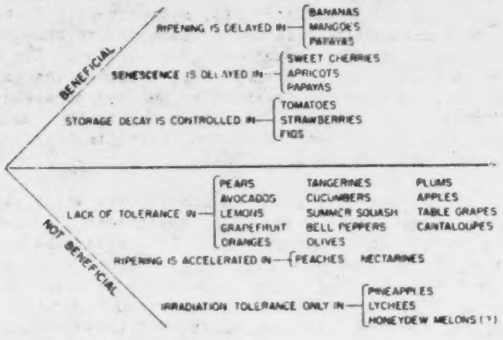
BENEFICIAL
RIPENING IS DELAYED IN— BANANAS, MANGOES, PAPAYAS
SENESCENCE IS DELAYED IN— SWEET CHERRIES, APRICOTS, PAPAYAS
STORAGE DECAY IS CONTROLLED IN— TOMATOES, STRAWBERRIES, FIGS
NOT BENEFICIAL
LACK OF TOLERANCE IN— PEARS, AVOCADOS, LEMONS, GRAPEFRUIT, ORANGES, TANGERINES, CUCUMBERS, SUMMER SQUASH, BELL PEPPERS, OLIVES, PLUMS, APPLES, TABLE GRAPES, CANTALOUPES
RIPENING IS ACCELERATED IN— PEACHES, NECTARINES
IRRADIATION TOLERANCE ONLY IN— PINEAPPLES, LYCHEES, HONEYDEW MELONS (?)

FIGURE 1. The response of 27 fruits to irradiation.

Source: Reprinted with permission from CRC Press, Inc., Akamine and Moy, 1983, p. 151.

can be misleading--or erroneous--because the effects of radiation not only vary between fruits; but for the same type of fruit, the exact effects depend on variety, maturity at harvest, initial quality, degree of microbial contamination, and postharvest handling procedures (Kader et. al., 1984, p. 1). Preharvest factors, such as rainfall, soil type, and fertilizer use influence the composition of the commodity and, in turn, may affect its response to irradiation. For these reasons, researchers often come up with conflicting recommendations on a commodity's tolerance and suitability for irradiation. Response to irradiation also depends on conditions at the time of treatment, such as irradiation at refrigerated temperatures or in the absence of oxygen. Extensive research on technical feasibility of specific applications is needed before commercialization is attempted.

For some fruits, researchers have been successful in lowering the needed dose by combining radiation with hot water treatment. For example, damaging doses of 600 krads (6 kGy) and higher were needed for significant decay control of papayas when irradiation was used alone. However, when irradiation was combined with a hot water dip treatment, the necessary dosage dropped to 75 krads (0.75 kGy) (Akamine and Moy, 1983, p. 142). As an added bonus, the salable life of papayas treated with this hot dip/irradiation treatment was three days longer than standard hot dip/fumigated papayas. Perhaps other fruits could benefit from a combination treatment.

II-7

Decontaminate Spices

Most spices imported from tropical countries are highly contaminated with molds, yeasts, and bacteria. Even small amounts of contaminated spices can cause problems when added to semi-processed and processed foods. Over the years, the food industry has used many methods to rid spices of these contaminants--dry and steam heat treatments, ultraviolet exposure, electron and microwave treatments, and chemical fumigation (Eiss, 1984, p. 362). Many of these treatments are insufficient or have serious drawbacks such as destroying flavor or color. The chemical fumigant most commonly used, ethylene oxide, is a hazard to workers exposed to the gas. The Occupational Safety and Health Administration has established a worker exposure limit of 1 part ethylene oxide per million parts air.

The use of ionizing radiation to sterilize spices has been the subject of research for 30 years. Treatment of spices to control microbial and insect pests is the only commercial use of irradiation on food in the United States today. Spices are also irradiated in several European countries and South Africa. The low moisture content of spices and dried herbs means their chemistry is less affected by irradiation than moist foods (Eiss, 1984, p. 362). Adequate control of contaminants can be obtained with 1,000 to 2,000 krads (10 to 20 kGy) (Urbain, 1978, p. 183). Vajdi and Pereira showed that gamma radiation was more effective than ethylene oxide in reducing the bacterial population in black pepper, paprika, oregano, celery seeds, allspice, and garlic (Vajdi and Pereira, 1973, p. 895). While ethylene oxide reduced the oil content of some of the spices and the brightness of paprika, irradiation caused insignificant changes. Researchers at McCormick and Company, Inc. found few chemical differences between spices irradiated at 1,000 krads (10 kGy) and the control spices (Eiss, 1984, p. 362). No significant sensory differences were found, except in one sample of Spanish paprika (ibid, p. 366).

Extend Shelf Life of Meat, Poultry, and Fish

Irradiation can also be used to extend the shelf life of fresh meat, poultry, and fish. Unlike fresh fruits and vegetables, animal and fish products are not "living" things whose ripening and respiration activities will be hampered by the irradiation treatment. However, to maintain acceptable organoleptic qualities, meat, poultry, and fish should be at refrigeration temperature when irradiated and shipped and stored under refrigeration. Also, off-flavors can be produced above certain levels. The threshold dose for detectable off-flavors varies with the product (table II-1).

The dominant spoilage organism in fresh meat, chicken and fish, Pseudomonas, is generally quite sensitive to irradiation, although some radiation resistant strains have been found (Grecz et al., 1983, p. 188). At the same time, it is important not to create an environment where pathogens not killed by the radiation, or introduced after irradiation, would grow out undetected during the extended storage. Preliminary studies indicate that exposure of very fresh fish to 100 to 250 krads (1 to 2.5 kGy) would double the 6 to 12 day refrigerated shelf life of most fish (table II-2). However, at doses above 100 krads there is a potential for Clostridium botulinum

Table II-1. Threshold Dose for Detectable Off-Flavor for Protein Foods from Various Animals Irradiated at 5° to 10°C (41° to 50 F)

Animal food	Threshold dose	
	krad	kGy
Turkey	150	1.5
Pork	175	1.75
Beef	250	2.5
Chicken	250	2.5
Lobster	250	2.5
Shrimp	250	2.5
Rabbit	350	3.5
Frog	400	4
Whale	450	4.5
Trout	450	4.5
Turtle	450	4.5
Halibut	500	5
Opossum	500	5
Hippopotamus	525	5.25
Beaver	550	5.5
Lamb	625	6.25
Venison	625	6.25
Elephant	650	6.5
Horse	650	6.5
Bear	875	8.75

Source: Urbain, 1978, p. 180.

(C. botulinum) bacteria to grow and produce toxin. C. botulinum type E is prevalent in most freshwater and marine sediments of North America and therefore should be considered a normal contaminant of all seafood (Eklund, 1982, pp. 107-8). In fresh fish, spoilage occurs before botulism toxin is produced. However, in fish irradiated at 250 to 300 krads (2.5 to 3 kGy) the normal spoilage flora, predominantly Pseudomonads, are reduced plus the longer shelf life permits the C. botulinum E to grow and produce toxin unless refrigerated at less than 3°C (36°F). Since refrigerated display cases in retail markets "can frequently be held at temperatures as high as 10°C (50°F)," this could be a health hazard (ibid, p. 108). Lower doses of 100 krads (1 kGy) or below appear to permit sufficient spoilage organisms to persist on some seafood items and provide an adequate margin of safety against botulism (Eklund, 1982, p. 110-1; Urbain, 1978, p. 193). Eklund points out that these results could vary depending upon the initial bacterial population prior to irradiation.

In contrast, C. botulinum in poultry appear to be injured by irradiation. Firstenberg-Eden et. al. found no toxin produced on chicken irradiated at 300 krads (3 kGy) and stored at 10°C (50°F) (1982, p. 869). Also, under severe

Table II-2. Optimal Radiation Dose Levels and Shelf Life at 33_0F 0.6_0C (33°F) for Fish and Shellfish in Airtight Cans

Seafood	Optimal irradiation dose		Shelf life */
	krad	kGy	weeks
Oysters (shucked)	200	2	3-4
Shrimp	150	1.5	4
Smoked chub	100	1	6
Yellow perch fillets	300	3	4
Petrale sole fillets	200	2	2-3
Pacific halibut steaks	200	2	2
King crab meat (cooked)	200	2	4-6
Dungeness crab meat (cooked)	200	2	3-6
English sole fillets	200-300	2-3	4-5
Soft-shell clam meats	450	4.5	4
Haddock fillets	150-250	1.5-2.5	3-4
Pollock fillets	150	1.5	4
Cod fillets	150	1.5	4-5
Ocean perch fillets	150-250	1.5-2.5	4
Mackerel fillets	250	2.5	4-5
Lobster meat (cooked)	150	1.5	4

*/ The shelf life of fresh fish without irradiation varies from 6-8 days to 12 days depending upon handling (Mid-Atlantic, Kroger, and Sea Grant, 1984). Source: Slavin, et. al., 1966, p. 365.

abuse temperatures of 50°C or 122°F enough of the natural flora had survived to spoil the chicken before botulism toxins were produced. 3/

Medium doses of radiation cause a significant extension of shelf life for fresh meat. To maintain acceptable organoleptic qualities the irradiation must be done at refrigerated temperatures of 0° to 4°C (32° to 39°F). The shelf life of vacuum packed beef cuts and hamburger can be doubled by doses of 200 and 300 krads (2 to 3 kGy), respectively (Niemand, et. al., 1983, p. 791). A recent study of hamburger from commercial outlets showed a virtual elimination of food spoilage organisms (Pseudomonads) and disease causing organisms (Enterobacteriaceae 4/) when treated with 250 krads and stored at 4°C under aerobic conditions for up to 11 days. C. botulinum growth was prevented by the Lactobacilli naturally present in hamburger.

Undesirable changes in meats naturally occur during storage that are not related to microbial spoilage. These changes include discoloration and off-flavors caused by exposure to air and "weeping" from lean tissue (Urbain,

3/ At 500 krad (5 kGy), an undesirable dose from a flavor standpoint, the natural flora would be reduced enough to be a potential botulism hazard at severe abuse temperatures.

4/ Enterobacteriaceae include E. coli, Shigella, Salmonella, Klebsiella, Yersinia, Proteus.

1983, p.3). Retail cuts of meat must receive appropriate chemical or packaging treatment in addition to the radiation to preserve color, texture, and flavor.

The shelf life of vacuum packed processed meats (precooked or chemically treated) is 30 days or more with good manufacturing processes. "Such stability is adequate for centralized processing and packaging into retail units and for distribution over large market areas" (Urbain, 1983, p.2). Thus, there seems little need for radiation to extend the shelf life of processed meats.

One of the major areas of irradiation research in the United States has been in the area of packaged meats and poultry storable at room temperature. Irradiation-sterilized meats and seafood have superior texture and nutritional content comparable to conventional canned foods (Urbain, 1978, p. 182, 212). High doses of 2,300 to 5,700 krads (23 to 57 kGy) would "commercially sterilize" the food, but precooking (heating to an internal temperature of 70° to 80°C or 158° to 176°F) to inactivate enzymes that would spoil the food and proper packaging are also needed (Josephson, 1983, p. 232). To minimize off-flavors, undesirable odors, and nutritional losses resulting from exposure to the necessary high doses, the foods are vacuum sealed and irradiated at -40° to -20°C (-40° to -4°F) (ibid).

Offer Public Health Benefits

Foods of animal origin are related to two thirds of reported food poisoning outbreaks in the United States (table II-3). Bacterial food poisoning generally takes the form of flu-like symptoms and short-term diarrhea. Viruses and intestinal parasites, such as tapeworms, are less frequently reported causes of human food poisoning. Medical complications from food poisoning are rare and primarily affect the very young, the elderly, and those in poor health. When complications occur, they are often serious and include arthritis, cardiac dysfunction, colitis, and meningitis (Appendix IV-A).

Current good manufacturing practices in food processing plants are designed to control the prevalence of foodborne pathogens by monitoring for organisms; using proper cooking, freezing, and refrigeration temperatures; keeping track of inventory and using food items before they spoil; and using good sanitation practices to minimize cross-contamination of foods (21 CFR 110).

Bacteria

The major bacterial causes of food poisoning are Salmonella, Campylobacter, Staphylococcus aureus, and Bacillus cereus (the latter two produce toxins which cause food poisoning).5/ Bacteria vary in their sensitivity to irradiation both by species (table II-4) and by the stage of their life cycle (Grecz, et.al, 1983, pp. 169-170). Generally, growing cells are 20 times more sensitive to radiation than dormant spores. Growing cells are probably more easily damaged by radiation because their high water content and active metabolism permit greater indirect damage by radiation. Under certain circumstances

5/ Minor bacterial culprits include: Shigella, Yersinia, Vibrio, Escherichia coli, Clostridium perfringens, Aeromonas hydrophila, Edwarsiella tarda, and Klebsiella (Mossel, 1984, pp. 91-2).

Table II-3. Foodborne Outbreaks by Cause, United States, 1981

Cause	Beef	Pork	Poultry	Other Meat	Seafood	Dairy Prod.	Salads	Fruits & Veg.	Baked Goods	Other Foods	Not Known	Total
Bacterial												
Bacillus cereus	0	0	0	0	1	0	0	0	0	5	2	8
Campylobacter jejuni	0	0	0	0	0	5	0	0	0	0	5	10
Clostridium botulinum	0	0	0	0	2	0	0	5	0	2	1	11
Clostridium perfringens	6	3	8	1	0	0	1	0	0	3	6	28
Salmonella	13	1	9	0	2	6	2	0	1	8	24	66
Shigella	0	0	1	0	0	0	3	0	0	0	5	9
Staphyloccocus aureus	3	11	7	1	1	3	4	1	7	1	5	44
Streptococcus Group A	0	0	0	0	0	0	0	0	0	0	2	2
Streptococcus Group D	0	0	0	0	0	0	0	1	0	0	0	1
Vibrio cholerae non-01	0	0	0	0	1	0	0	0	0	0	0	1
Vibrio parahaemolyticus	0	0	0	0	0	0	0	0	0	0	2	2
Yersinia enterocolitica	0	0	0	0	0	0	0	1	0	1	0	2
Other	0	0	1	0	0	0	0	0	0	0	0	1
Subtotal	22	15	26	3	7	14	10	8	8	20	52	185
Chemical												
Ciguatoxin	0	0	0	0	15	0	0	0	0	0	0	15
Heavy metals	0	0	0	0	0	0	0	0	0	2	0	2
Monosodium glutamate	0	0	0	0	0	0	0	0	0	2	0	2
Mushroom poisoning	0	0	0	0	0	0	0	11	0	0	0	11
Scombrotoxin	0	0	0	0	7	0	0	0	0	0	0	7
Other	0	0	0	0	0	2	1	1	4	6	0	14
Subtotal	0	0	0	0	22	2	1	12	4	10	0	51
Parasitic												
Giardia lamblia	0	0	0	0	0	0	1	0	0	0	0	1
Trichinella spiralis	1	5	0	0	0	0	0	0	0	0	1	7
Subtotal	1	5	0	0	0	0	1	0	0	0	1	8
Viral												
Hepatitis A	0	0	0	0	0	0	0	0	0	3	3	6
Subtotal	0	0	0	0	0	0	0	0	0	3	3	6
Confirmed outbreaks	23	20	26	3	29	16	12	20	12	33	56	250
Unknown outbreaks	11	2	8	0	8	2	9	2	0	8	268	318
Total outbreaks	34	22	34	3	37	18	21	22	12	41	324	568

Table II-4. Decimal Reduction (D_{10} value)1/ for Some Microorganisms

Species	Dose	
	krad	kGy
Pseudomonas spp.	10 - 20	.1-.2
Escherichia coli (aerobic)	12 - 35	.12-.35
Escherichia coli (anaerobic)	20 - 45	.2-.45
Salmonella spp.	20 - 50	.2-.5
Streptococcus faecalis	50 - 100	.5-1
Fungus spores (Penicillium, Aspergillus, etc.	50 - 70	.5-.7
Bacillus pumilus (spores)	ca. 170	ca. 1.7
Clostridium sporogenes	160 - 220	1.6-2.2
Clostridium botulinum	150 - 250	1.5-2.5
Micrococcus sodonensis	ca. 195	ca. 1.95
Micrococcus radiodurans	>500	>5

1/ The D_{10} value is just a starting point for reducing the quantity of organisms by 90%. To achieve the same sterility as canned foods a dose of 12 times higher may be necessary (Josephson, 1984, pp. 234-6).
Source: Langerak, 1982, p. 49.

growing cells may become even more resistant to radiation than spores. Some cells have an exceptional capacity for repairing injuries from radiation. Also, pathogens in frozen or dehydrated foods are protected to some degree from the damaging effects of radiation. The nuclei of yeasts and molds represent large radiation targets, making yeasts and molds generally more sensitive to radistion.

Campylobacter and Yersinia are relatively sensitive to irradiation, and Maxcy has concluded that "a low dose of 200 krad would essentially eliminate these common bacteria of public health significance" (Maxcy, 1983, p. 210). Salmonellae are moderately sensitive to irradiation (table IV-11).

Much radiation research has focused on radiation-resistant bacterial species and spores which can grow in foods under special conditions. The spore formers Clostridium and Bacillus have been of major concern because of their "exceptionally high resistance to radiation, heat, and chemicals" (Grecz, et. al., 1983, p. 176) and their association with food spoilage and health hazards. There is great variation among "strains belonging to the same species or even to the same seriological type" (ibid, p. 181).

One area for potential concern when irradiating animal products for bacterial control would be the development of a radiation-resistant organism. Radiation-resistant vegetative (growing) bacteria occur in environments with high natural or artificial radiation. Their resistance can be higher than the resistance exihibited by spores, but fortunately most are not of public health significance (Grecz, et. al., 1983, p. 200). In the laboratory, radiation-resistant mutants of Salmonella and E. coli have been developed by repeated exposure to radiation (ibid, pp. 187-8). However, most researchers

believe pathogenic radiation-resistant mutants would not be a serious problem in commercial scale food irradiation facilities (ibid).

Parasites

Sensitivity to radiation varies greatly among parasites. Trichinae are among the most sensitive, and Anisakis (a fish parasite) are among the most resistant. 6/ A dose of 1,000 krads (10 kGy) is lethal to all foodborne parasites. The off-flavors produced by a dose needed to kill all parasites would be noticeable for most foods (table II-1).

However, applications in the United States could include 1) low doses under 100 krads (1 kGy) of radiation to kill sensitive parasites in foods, 2) low doses to sterilize a parasite so that it will not reproduce in the human host and cause a serious health problem, and 3) high doses to kill pathogens in animal feeds or sewage to break the cycle of some parasites re-entering the human food chain.

Viruses

Viruses are highly resistant to radiation because they are among the smallest biological entities known. Bacteria, yeasts, and molds can be benefical, neutral or harmful, but viruses are usually harmful to their host since they are parasites at the molecular and cellular level. Viruses, transmitted through foods, have caused human diseases such as hepatitis and polio (Grecz et. al., 1983, pp. 205-6).

Conventional heat processing easily inactivates viruses. Therefore, the preliminary heat treatment used to inactivate enzymes in radiation-sterilized foods would also "inactivate most of the foodborne viruses" (Grecz et. al., 1983, p. 209).

In contrast, low to medium level irradiation alone will not produce adequate health protection benefits from reduction of viruses. Another concern is that irradiation of viruses could produce potentially harmful mutants, but Grecz, Rowley and Matsuyama conclude that the restrictions for successful mutations are "rather severe and they make it extremely unlikely that potentially harmful mutants can be produced from a radiation damaged population" (1983, p. 209).

In summary, many food poisoning bacteria are sensitive to low dose radiation and their numbers could be significantly reduced by radiation processing. Bacterial spores would not be destroyed except at sterilization doses, and thus current control procedures would need to be maintained to control bacterial spore-formers. Further, the irradiation facility should monitor for the unlikely development of radiation resistant bacterial mutants. Common parasites vary greatly in their susceptibility to radiation, but many can be controlled with low to medium doses. Viruses are not affected by these levels of radiation.

6/ For a detailed listing of protozoa and helminth sensitivity to radiation see Tables 1 and 2 in King and Josephson, 1983, pp. 249, 251-2.

Irradiation to achieve public health benefits must be used on those foods and with pre and post treatments that do not produce undesirable changes in the food. For example, turkey is especially sensitive to radiation and develops off-flavors at doses as low as 150 krads (1.5 kGy). Also, it is important not to create an environment where pathogens not killed by the radiation, or introduced after irradiation, would grow undetected during the extended storage.

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III. CONSUMER ACCEPTANCE, POTENTIAL BENEFITS, AND LABELING

While irradiation may be technically feasible for a number of foods, consumers must be willing to purchase irradiated food. First and foremost is whether irradiated food is safe and wholesome; are consumers confident that public regulators are adequately addressing consumer safety concerns and not dominated by industry interests ? Also, the price must be competitive with non-irradiated food or the benefits offered by irradiation sufficient to offset any price premium. Integral to consumer acceptance is labeling--U.S. consumers want to be informed and to be able to choose or refuse irradiated food.

Consumer Acceptance

Consumer acceptance and willingness to purchase irradiated foods are critical to the commercial success of food irradiation. Wide fluctuations in sales or consumer boycotts increase irradiation costs significantly if production lines are operated at less than full capacity (see chapter V). Public acceptance depends on the benefits of radiation treatment being passed on to consumers. If spoilage reduction is the only benefit, then consumers should receive some of the extended shelf life in their own homes or see a reduction in price (reflecting cheaper handling methods or transportation modes made possible by the longer shelf life).

American consumers are not generally opposed to new food technologies. They have been quick to accept microwave ovens, even at the considerable expense of purchasing a special oven and the adjustments to changes in taste, texture, or color of some foods. 1/

Before consumers will make a decision as to whether the benefits offered by irradiation are appealing, they must be confident that irradiated foods are safe to eat. The major concerns of consumers are (1) does it make food radioactive? (2) does it lessen the nutritional quality of the food? and (3) is the food safe to eat, are there any toxic concerns? (Urbain, 1984, p. 7). Our purpose is to discuss these issues in general terms. This is not a review of all safety concerns, some of which are resolved and others unresolved. Chapter II includes additional safety concerns.

Radioactivity

Consumers do not need to fear that irradiation will cause their food to become radioactive above normal background radiation (49 FR 5716). The photons from cobalt and cesium sources do not have sufficient energy to

1/ About half the homes in the United States have a microwave oven ("The New," 1985, p. 644).

excite the nucleus and induce radioactivity.2/ Electrons from accelerators operating at less than 10 MeV will not have sufficient energy to induce radioactivity. X-ray machines operated at 5 MeV are below the energy threshold necessary to induce or promote radioactivity. FDA has approved electron beam machines operating at 5 MeV and is considering allowing machines operated at 10 MeV as well as X-ray sources operated at 5 MeV and below (49 FR 5720).3/

Nutrition

While the nutrients in each food respond differently to irradiation, in general, nutrient destruction appears no greater than cooking or freezing (Josephson, et. al., 1978, p. 299). The FDA is giving particular attention to vitamin A and carotene, vitamin E, vitamin C, vitamin B-12, thiamin (B_1), and vitamin B-6 because some published studies have shown losses in irradiated products (Brunetti, et. al., 1980, p. II-4).4/ The retention of different B vitamins in beef after freezing, heat sterilization, or irradiation sterilization with cobalt or electron beam sources is shown in table III-1. Immediately after processing, cobalt irradiation preserves more of these four B vitamins than canning. After 15 months of storage the cobalt-irradiated beef had more thiamin (B_1), the same amount of riboflavin (B_2), but less niacin and B_6 than the canned beef. The dose applied in table III-1 is much greater than the 100-krad (1 kGy) dose FDA is considering. At lower irradiation doses nutrient destruction would be even less as there is a roughly linear relationship between irradiation dose and nutrient destruction (Brynjolfsson, 1979, p. 10).

Table III-1. B Vitamin Destruction in Beef When Frozen, Canned or Irradiated with Cobalt-60 or Electron Beam

B vitamin	Storage Period	Treatment			
		Frozen	Heat Sterilized	Irradiated 1/ Cobalt 60	Irradiated 1/ Electron
	months	mg/kg			
Thiamin (B_1)	0	0.97	0.63	0.83	0.77
	15	0.68	0.14	0.21	0.26
Riboflavin (B_2)	0	2.80	2.63	2.83	2.60
	15	1.69	2.60	2.60	1.46
Niacin	0	48.6	48.1	48.8	46.8
	15	57.2	54.9	50.1	44.5
Vitamin B_6	0	2.50	2.13	3.93	5.20
	15	0.97	0.57	0.35	0.42

1/ Irradiated at 4,700 to 7,100 krads (47 to 71 kGy).
Source: Josephson, et. al., 1978, p. 307.

2/ MeV is the abbreviation for million electron volts. One MeV equals 1.6×10^{-6} erg (Goresline, 1970, p.7).

3/ The conversion efficiency from electrons to X-rays of an X-ray machine operated at 10 MeV is about double the efficiency of an X-ray machine operated at 5 MeV (table VI-2). Hence there is a strong economic incentive to operate above the proposed regulatory limit and at these higher levels there is the possibility of induced radioactivity in food.

4/ The loss of vitamin K is not considered significant because humans can produce their own vitamin K.

USDA's Food Safety and Inspection Service (FSIS) has requested further scientific work on thiamine losses in pork irradiated at refrigereated temperatures--most of the earlier work was done with frozen pork which minimizes vitamin losses. Preliminary results show losses of 54 percent at the 100 krad level ("Thamine," 1985, p. 35). Experiments are also planned to determine whether irradiation using cobalt and cesium produces greater vitamin destruction than using electron beam (ibid).

Safety

The public depends upon FDA to carefully scrutinize the safety of irradiated foods. Although the Codex Alimentarius Commission has unconditionally approved the irradiation of food up to 1,000 krads (10 kGy) as being safe for general applications, the FDA has taken a conservative approach and is considering approval of the 100 krad (1 kGy) level first; later, FDA may consider higher levels (chapters VIII and XI). Public confidence in FDA and the regulatory process is crucial to acceptance of irradiated food. It is impossible to expect consumers to evaluate the many hundreds of research papers published on the safety of irradiated foods and make proper judgments about safety (Barna, 1979; Reber, 1966).

Even with well designed studies, results can vary with the temperature during irradiation, the atmosphere in the irradiation chamber (oxygen versus an inert gas), the duration of irradiation, and the storage time of the irradiated food. Furthermore, the chemical constitutents within a food vary with its genetic stock, the soil it is grown in, the amount of rainfall, etc. This variability has made it difficult for scientists to replicate experiment results and makes consumer acceptance problematic because the scientific truth is multi-faceted and sometimes ambiguous. Consequently scientific data can be selectively used by advocates and opponents to support their respective views. 5/

In 1982, an FDA Task Group for the Review of Toxological Data on Irradiated Foods examined all available toxicological studies. Out of 441 toxicology studies, the Task Group eliminated all but five from review because of missing

5/ The private sector is beginning to educate the public about food irradiation. Professional and trade organizations have sponsored seminars and press briefings on food irradiation developments. The Council on Radiation Applications (CRA), formed in 1984 under auspices of the Atomic Industrial Forum, publishes monthly a newsletter on food irradiation and has produced written and audiovisual materials. The food industry has its own newly-formed public education group called the Coalition for Food Irradiation. As of December 1985, 31 associations and companies were members. The Coalition's mission is to educate consumers, inform legislative and regulatory decision makers, and develop opportunities where useful dialogue about food irradiation concerns can take place.

Activists opposed to food irradiation organized a National Coalition to Stop Food Irradiation in 1985 which puts out a newsletter, testifies at hearings, and encourages the formation of local grassroots groups around the country.

data or inadequate experimental design. These five long term studies appeared to support safety of irradiated foods. 6/ Some of the problems in the animal feeding studies were: animal health responses due solely to feeding an unbalanced diet; absence of vitamin supplements in the diets to replace the vitamin K and thiamine destroyed by irradiation; spoiled irradiated food fed to animals; improper control group procedures; lack of double blind procedure to eliminate researcher bias either for or against irradiation; inadequate sample size; and inadequate length of time for a study (van Gemert, et. al., 1982). According to FDA, although most of the studies were inadequate by present day standards, many contain elements which, when viewed collectively, allowed the conclusion that irradiation of foods at low levels (100 krads or 1 kGy) did not appear to show adverse toxicological effectson the experimental animals. If a potent toxic material were present in irradiated foods at any level of toxocological significance, some consistent toxicological signs would or should have been manifest in the studies reviewed.

Potential Benefits to Consumers

Irradiation of food offers three types of economic benefits to consumers: reduced spoilage and consequently a longer shelf life, public health protection, and improved product characteristics. This section describes potential benefits which may or may not outweigh perceived risks or costs in various applications. More details on irradiation's benefits and limitations are provided in chapter II, and some alternatives to irradiation are discussed in chapter VII.

6/ The final report of the Task Group stated: "Based on our extensive review of the data, we conclude that studies with irradiated foods do not appear to show adverse toxicological problems. The lack of effects however could have resulted from the dietary problems, inadequacies of experimental design, ambiguity and non-reproducibility of the available data on irradiated foods. Studies of sufficiently high quality to support the safety of irradiated foods treated at high irradiation doses which constitute major contributions to the daily diet for long-term use are also not available. However, traditional toxicology (eg. subchronic and chronic) studies may not provide meaningful answers to safety questions regarding these types of irradiated foods. There are two major reasons for this situation. First, nutritional imbalances in the animal's diet due to feeding high levels of irradiated and non-irradiated foods would tend to mask any potential toxicological manifestations. Secondly, the extreme dilution of the potentially toxic unique radiolytic products in proportion to the high levels of irradiated foods themselves, would result in an inability, as in traditional toxicology testing, to exaggerate the dose of the test compound. For these reasons it would be difficult to devise a traditional toxicology study of sufficient sensitivity to provide assurances of safety for the population exposed to unique radiolytic products from irradiated foods constituting a major portion of the total diet. ...We therefore agree with the committee's (Brunetti, et. al.) conclusion that food irradiated at doses not exceeding 100 krad is wholesome and safe for human consumption and should be exempt from any toxicology testing requirements"(van Gemert, et. al., 1982, p. 2-3).

Shelf Life Extension

One commonly cited benefit of food irradiation is the extension of shelf life by reducing spoilage loss. For tropical fruits which tolerate radiation well irradiation has been suggested as a method to destroy parasites and fungi and to delay ripening and aging. A reduction in spoilage loss has also been postulated for fresh fish, red meat, and poultry. By reducing spoilage bacteria, irradiation could extend the shelf life of these products. Estimates of food losses during transportation, wholesaling, and retailing are about 5 percent for fresh beef and around 10 to 15 percent for produce (table III-2). To the extent these losses are caused by spoilage, irradiation could potentially reduce such losses. However, fresh meats and produce also suffer from cutting and trimming losses which may not be reduced by irradiation.

Table III-2. Estimates of Food Losses During Distribution 1/

Food Product Group	Losses	Product Group's Proportion of Super-Market Food Sales
	percent	percent
Fresh Beef	4.8	13.4
Produce	9.04 - 16.61	9.8
Dairy Products	.63 - 3.50	15.2
Dry Grocery	.382	36.2
Frozen Foods	.98 - 2.85	8.1
Bakery Goods	1.05 - 12.48	4.7
Deli Foods	4.91 - 7.40	5.2
Totals	1.77 - 3.60 2/	92.6

1/ Transportation, wholesaling and retailing.
2/ These figures are based upon a range of 1977 dollar losses — $1,590 to $3.234 billion -- as a percentage of 1977 total supermarket food sales.
Source: Pierson, et. al., 1982, p. 5.

In addition, the major causes of losses shared with other foods are improper temperature and moisture control, improper or abusive handling, poorly designed packaging, and ineffective management (Halloran, 1981, p.5). Irradiation will not eliminate these problems. In fact, in some cases irradiation can increase a food's sensitivity to improper handling and storage. While irradiated meat and poultry will have a longer shelf life even at a slightly elevated temperature, some irradiated fruits become more susceptible to mechanical injury or cold temperatures.

Irradiation of fish and shellfish can double shelf life from one week to two weeks and permit marketing of fresh seafood in major cities in the middle of the United States. Several East coast supermarkets have found that adding fresh seafood counters adds customer traffic and increases sales (Elson, 1984, p. 32). Irradiation has the potential to further expand the demand for properly refrigerated fresh seafood by: 1) making fresh seafood available in inland urban supermarkets where canned or frozen are the only choices, 2) increasing the quantities of fresh seafood purchased by supermarkets which currently underbuy because of fear of expensive spoilage losses, and 3) stabilizing the quality of fresh seafood at a high level.

Almost all 400 repondents to a Consumer Network questionnaire indicated an interest in food products that stay fresh longer (Titlebaum and Dubin, 1983, p. 223). Over 50 percent of respondents expressed interest in longer freshness for milk, fruits and berries, and other dairy products. For lunch meats, poultry, fish/seafood, and regular meats, over 40 percent expressed interest (ibid). However, it is not clear whether extending shelf life with irradiation would be perceived as increasing freshness; any current treatment to lengthen shelf life is perceived as "processing" and therefore the food is no longer considered "fresh" (ibid, p. 226).

Public health protection

The primary vehicles for foodborne illness are meat, poultry, and fish (see table II-3 in chapter II). Fresh fruits and vegetables are very infrequently the cause of foodborne outbreaks and thus are not discussed in this section.

The dominant spoilage organism in fish, Pseudomonas, can be a health hazard to persons in a weakened condition but is normally destroyed by our immune system, and thus is not considered a health concern (Nordbring, 1982, p. 2010; Nickerson, et. al., 1983, p. 33). Several organisms causing intestinal problems have been associated with seafood. For example, Vibrio is the most common foodborne pathogen in Japan (Nickerson, et. al., 1983, p. 31; Abeyta, 1983, p. 901). For raw products--oysters and clams on the half shell, sushi,

and other Japanese versions of raw fish--irradiation at medium doses (around 100 to 250 krads or 1 to 2.5 kGy) could reduce some of these health concerns (Nickerson et. al., 1983, pp. 30-31; Raw, 1985). However, some parasites such as Anisakis would not be destroyed and would remain a health concern. More importantly, irradiation of seafood could increase the risk from Clostridium botulinium type E if irradiated fish are not kept refrigerated at 3°C (37°F) or less.

A study contracted by the Department of Energy estimated that about 110,000 trichinella infected swine are slaughtered each year in the United States resulting in about 150,000 to 300,000 human trichinosis cases annually (CH2M Hill, 1983, p. 3-5). The vast majority of these infections are so mild that they are not noticed. Thus, public health protection benefits from exposing pork to low doses of radiation to inactivate the trichinosiscausing parasite would be low (chapter IV). However, simultaneous destruction of Toxoplasma gondii, a cause of mental retardation in fetuses, would have significant benefits (chapter IV).

Irradiation can offer public health benefits by reducing the numbers of disease-causing microorganisms in fresh chicken, such as Salmonella and Campylobacter. Detailed public health protection benefits are calculated for disease-reduction in irradiated fresh chicken and discussed in the next chapter.

Irradiation of beef offers potential health protection benefits. For example, at medium levels (250 to 500 krads or 2.5 to 5 kGy) Salmonella and Clostridium perfringens which cause stomach flu-like symptoms are greatly reduced. While most of these pathogens are destroyed by thorough cooking, rare or raw meat could still harbor them. Some pathogens, such as C. perfringens, have heat-resistant strains which could remain except in pressure-cooked meats (Sours, 1981, p. 276). Potential benefits for a reduction of Salmonella and tapeworm in beef using irradiation are discussed in chapter IV.

Irradiation can be used to decontaminate raw spices that are highly contaminated with molds, yeasts, and bacteria. This contamination can cause spoilage and health problems when the spices are added to semi-processed and processed foods. Many decontamination treatments are insufficient or have serious drawbacks (Eiss, 1984, p. 362). Irradiation with doses of 1,000 to 2,000 krads (10 to 20 kGy) provides adequate control and has insignificant effects on the spices' oil content and color.

Irradiation can offer public health benefits by substituting for potentially harmful chemicals currently used as fumigants and preservatives. Irradiation is suggested as a non-chemical alternative to ethylene dibromide (EDB) once used to fumigate fresh produce and grain. EDB was banned as a fumigant for most commodities by the U.S. Environmental Protection Agency effective September 1, 1984. These fumigants are especially hazardous to the workers applying the chemicals or gases.

Studies have shown that irradiation sterilization with a dose of 3,000 krads (30 kGy) reduces residual nitrite in bacon prior to frying (Fiddler, et. al., 1981). Researchers at USDA's Eastern Regional Research Center in Philadelphia are exploring the use of medium doses of radiation to reduce the amount of nitrite used in bacon (see chapter X).

Improved Product Characteristics

By eliminating the trichinosis danger from eating pork, one consulting firm predicts an increase in demand for pork (CH2M Hill, 1983, pp. 8-13). This demand shift is hypothesized to occur largely because people prefer to eat trichinae-safe pork 7/ and also because it could be cooked less and remain juicier and be more competitive with beef steaks. The CH2M Hill study assumes that consumers would readily accept irradiated pork. However, at a minimum, an extensive educational and promotional campaign would be needed to introduce the process and, even then, irradiation would be a roadblock to purchases by some people.

Varying doses of radiation can be applied to foods to achieve different desired qualities. Urbain (1978, p. 204-205) discusses some of these improvements including: increased loaf volume for bread made from irradiated wheat, tenderization of beef, and shortened rehydration time for dehydrated vegetables. Research at the University of California at Davis has shown that irradiating red wines can speed up the conventional aging process. Additionally, irradiation can reduce the amounts of gas-causing sugars in beans, increase the juice from grapes, and improve the quality of canned fruits and canned meats (FAO/IAEA consultant, 1982). For the tropical fruits where irradiation can be used to delay ripening, irradiation might allow fruits to be harvested closer to full ripeness with superior taste. In this case, irradiation would be used to slow the ripening process and allow time for marketing.

U.S. Consumer Surveys

Because the only irradiated foods in the U.S. marketplace are micro-ingredients, consumer acceptance of this new process must be estimated through consumer interviews. Consumer surveys can measure awareness and reaction to food irradiation; but the results do not guarantee that respondents voicing little or no concern with the process will actually purchase or consume irradiated foods, and vice versa.

A survey of 1,000 consumers was conducted for the Department of Energy and the National Pork Producers Council in February 1984 (Weise Research Assoc., Inc. 1984). After being asked a series of questions about their concern with chemical preservatives and sprays, foodborne diseases, and spoilage loss of foods, consumers were asked whether they had a major, minor, or no concern about a new method to kill harmful organisms in food. Between 33 and 43 percent of the respondents said they had a major concern about this new process, depending on which of three terms were used--gamma waves, irra-

7/ It is unlikley that FSIS will permit the use of the phrase "trichinosis-safe" because negative labeling claims are not permitted unless the converse of the claim is typical and this is not the case with trichinae infected hogs ("FSIS Sets," 1985, p. 3).

diation, and ionization (ibid, p. 28). The term "irradiation" elicited the greatest number of major concern responses. This finding emphasizes how important terminology is in consumer acceptance. A little less than 25 percent of the consumers said they had heard of the process prior to the interview (ibid, p. 26).

Respondents were asked to volunteer opinions about possible advantages this new process could offer. The most common answer was "don't know" (43 percent), but other respondents mentioned less chance of sickness from food (11 percent), elimination or reduction of chemicals (10 percent), and longer shelf life (6 percent) (ibid, p. 34). Thus, there is opportunity to introduce people to irradiation's potential benefits.

Table III-3. Volunteered Concerns with Irradiation Using Three Descriptive Terms

	Description of Concept			
	Gamma Waves	Irradiation	Ionization	Combined-All Descriptions
Number of Respondents	336	346	318	1,000
Volunteered Concern		Percent		
Don't know	29	26	38	31
Radiation - if left in food, the amount, the word	16	24	8	17
Nothing, none	13	13	10	12
Amount of testing done, if proven safe	9	9	9	9
Might be harmful to people	7	11	7	8
Effect on the food	9	5	9	8
New, need to know more about it	9	6	9	8
Possible side effects	7	5	8	7
Possible cancer-causing	4	8	4	6
Long-term effects on people	5	3	3	4
Not natural, we grow own food	2	2	4	3
Cost efficiency, cost	2	2	--	1
How long effective, shelf life	1	1	2	1
All other concerns	1	1	2	1
Totals 1/	114	116	113	116

1/ Percentages total to more than 100 percent due to multiple replies. Fifteen percent of the total sample gave more than one concern.
Source: Weise Research Assoc., Inc., 1984, p. 36.

Respondents were also asked what concerns they might have with this process. The volunteered concerns varied depending on which descriptive term was used in the earlier question on initial concern (table III-3). Concern over radiation left in the food showed the most variability. Twenty-

four percent of the people who were read "irradiation" listed this concern versus only 8 percent of the people read "ionization" (ibid, p. 36). Other concerns with irradiation included its possible harm to people, side effects, insufficient testing, its effect on the food, and lack of information about the process (ibid, p. 36). Interestingly, a greater portion of the sample (55 percent) expressed a major concern about chemical sprays used on fruits and vegetables than the number of people (38 percent) expressing the same level of concern about irradiation. It is important to remember that this survey was conducted the same month that the controversy over ethlene dibromide (EDB) was publicized by the media. A characteristic of consumer surveys is their sensitivity to concerns at the time of the interview.

When survey participants were asked which factor out of a list of eight is the most persuasive attribute in favor of food irradiation, the most often selected reasons were no radiation in the food, no chemicals in the food, irradiated foods being fed to patients with immune problems (cancer patients on special diets), and FDA approval. Figure III-2 shows the percentage of respondents citing each factor as the most persuasive.

Information on U.S. consumers' awareness of food irradiation was gathered as part of a 1985 Food Marketing Institute national survey on consumers' attitudes and shopping practices (Food Marketing Institute, 1985). Twenty-nine percent of the 1,005 respondents had heard of irradiation (compared to 25 percent in the 1984 survey). When asked which method they would prefer--irradiation or chemical preservatives--39 percent of those who have heard of irradiation said they would prefer its use over the use of chemical preservatives. Among the respondents who had not heard of irradiation, a greater portion were uncertain which technique they prefer, but more (28 percent) prefer chemical preservatives than prefer irradiation (22 percent). These findings suggest irradiation may become more acceptable as people learn more about the technology.

To better understand U.S. consumers' attitudes toward food irradiation, the Department of Commerce is partially funding a market research study to be concluded by the end of 1985 (see chapter X).

Labeling

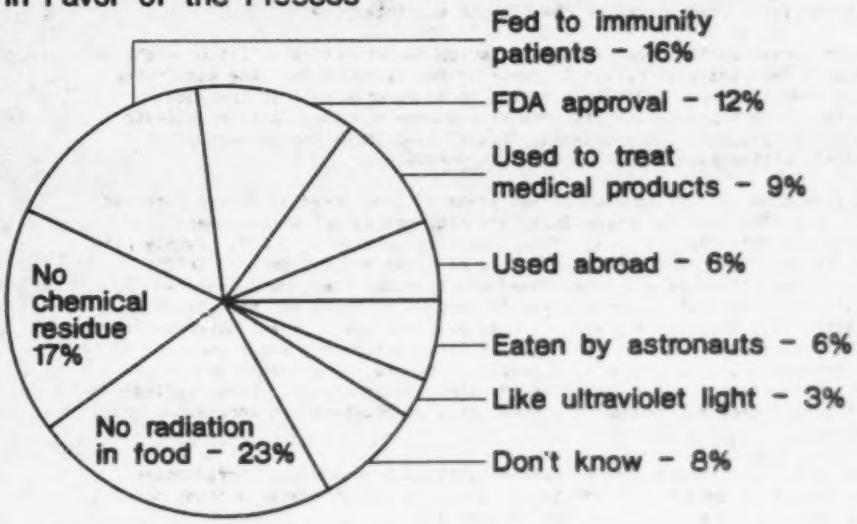
There is general agreement internationally and in the United States that irradiated wholesale food ingredients and products should be labeled to alert purchasers of that fact. Otherwise product characteristics could be adversely altered by re-irradiating and inadvertent exposure to excess radiation. FDA currently requires wholesale packages and invoices or bills of lading for bulk shipments to bear the statement "treated with ionizing radiation--do not irradiate again" (21 CFR 179).

There is less agreement internationally on retail labeling. Some of the labeling issues raised at a 1982 international meeting on consumer acceptance of irradiated food are listed in table III-4. Some feel that labeling is not necessary because irradiation is a process like canning, freezing, or pasteurization and that labeling gives the connotation that irradiation is a food additive. Some food processors are concerned that consumers will shun food

III-11

Figure III-2

Most Persuasive of Eight Attributes
In Favor of the Process


Fed to immunity patients - 16%
FDA approval - 12%
Used to treat medical products - 9%
Used abroad - 6%
Eaten by astronauts - 6%
Like ultraviolet light - 3%
Don't know - 8%
No radiation in food - 23%
No chemical residue 17%

100% represents those respondents with at least one factor rated as reducing their concerns (N=897).

labeled as irradiated because of the unfounded fear that it is radioactive. Others think that labeling can be turned into a positive story (Irradiated, 1985). Consumer advocates generally feel that consumers have the right to know if a food has been irradiated.

Table III-4. Pros and Cons of Retail Labeling of Irradiated Foods.

Against Labeling	For Labeling
Irradiation is a physical process and should not be required to state anything on the package.	Informs consumers, prevents suspicion and accusation of lack of integrity and honesty.
Misleading words or statements must not be made on the label.	Consumers have a right to be informed and choose.
Labeling is not a vehicle for education.	Forces industry and others concerned to promote educational programs.
Limited space on the label precludes adequate information and description of the process.	Only if the product is labeled can consumers identify and prefer the irradiated product.
Industry may use labeling to overpromote quality (improvements).	
Because of the objection in some countries, it will prevent the maximization of the process and its benefits.	

Source: FAO/IAEA consultant meeting, October 1982, pp. 20-21.

At the March 1985 meeting of the Codex Committee on Food Labelling 7/, the members decided that irradiated foods should be identified, but did not stipulate what form this identification should take (Chapter IX). Current FDA regulations require retail labeling of irradiated foods. However, the latest HHS proposal which has yet to be approved by the Office of Management and Budget (OMB) is to use "Picowaved" on the label of irradiated products ("HHS", 1985, p. 845). 8/ Earlier statements by FDIS indicated their intention

7/ The Codex Committee on Food Labelling is a committee of the Codex Alimentarius Commission, an international group that develops global food standards.

8/ Focus group discussion of operators of Stop and Shop Supermarkets indicated a preference for "straight forward terminology and explanation of the process to be included on food labels and at the point of sale. They felt that euphemisms hide information from the public. However, the term 'radiation' raises a red flag in consumers' minds, because of the heightened sensitivity to accidents at nuclear power plants and problems with disposal of radioactive products" (Tillebaum and Duvick, 1983, p. 231).

to require "Caveat[illegible]" on labels of dark and poultry products that exceed [illegible] ppm.[illegible] 1985, p. 1). In no likely case did all requirements for [illegible] warning or [illegible] and FSIS will automatically agree on the best policy.

The concept of labeling complicated foods consumed over many days is an issue that is yet to be addressed. There are some precedents for such labeling in the United States: manufacturers using dangerous classes of colors are required to state this on their labels, and labeling for nutrition is under consideration.

If certain labeling on food packages and in restaurants is adopted, the specific words chosen could be very important to consumer perceptions. A [illegible] survey on five labeling phrases found that consumers "overwhelmingly preferred" either "Cooking Oxide" or "Poisonous Chemical to Carcinogen" [illegible], 1985). "Produced with cancer causing agent" and a skull [illegible] were preferred when "Carcinogen" or "Contains cancer causing substance."

The importance of labeling to consumer acceptance in this study by the Food Legislation [illegible], 1985). Instead of a series of small [illegible] under different labels, the Food Legislation a carcinogen with each [illegible] substances. Noting the various drugs, [illegible] substances were differentiated only by the [illegible] legislation spoke out [illegible] [illegible] after food quality a new EPA grade package was introduced with the label "Carcinogen Substances." Consumer [illegible] were unaware "trace quantities" and [illegible] believed the trace's state of the market. [illegible] to whether consumers thought the [illegible] substances were not [illegible] or whether they were reacting to the [illegible] that the substances were [illegible].

Japan's prohibition of chemical [illegible] to ensure [illegible] of products led to opening a private investigation in [illegible] to EPA. [illegible] in Japan are labeled as such on the products [illegible]. If so, the necessary [illegible] of consumers began to protest. [illegible] by publishing articles in their newspaper and [illegible] consumer hotlines and by [illegible] the press about [illegible] to begin to provide information to government agencies, consumers' organizations, industry, and agricultural [illegible] on the benefits of [illegible]. By the efforts of the Japanese began and "Public Groups in Japan [illegible] to work to handle [illegible] problems, as [illegible] efforts of [illegible] [illegible], 1985, p. 10). Subsequently, most of the products in the [illegible] Middle-Eastern Japan, France Africa, and [illegible] to not have a [illegible] labeling they are made from [illegible] products [illegible], 1985).

In contrast, the South African experience has been more positive in several respects:

(1) An information and publicity campaign was an integral part of the Food [illegible] of [illegible] products, [illegible], [illegible], and [illegible]

[illegible] of [illegible] of [illegible] are labeled with a [illegible] as well as the U.S. [illegible] [illegible], 1985).

in 29 stores of 3 supermarket chains during 1979 (van der Linden, 1983, p. 14). Consumer response was 91 percent positive (van der Linden and Brabrice, 1983). However, consumers would not buy the irradiated foods unless it was cheaper, of superior quality, or had a longer shelf life (van der Linden, 1983, pp. 19-21). The last two benefits can only be captured by irradiating high quality foods.

(3) Products sold after the test marketing are not required to state that they have been irradiated.

(3) An outbreak of salmonellosis caused by one of the fastest growing items on the retailer's shelf, ruckfoe tea, led the manufacturers in South Africa to pull it off the shelves. They sought government approval to irradiate the tea and have launched a new advertising campaign. The campaign uses the slogan, "Ruckfoe Gets The Green Light," which features a green radiation symbol but does not use the word "irradiated" because "anything which brings to mind radiation has very distasting connotations" says Toby Smith, managing director of T.W. Backwells, a major supplier of ruckfoe tea (Bour, 1985, p. 27). Smith is expecting sales of ruckfoe tea to reach their previous levels in a year or so.

The marketing experience in the Netherlands, Japan, and South Africa shows that labeling is an important, potentially controversial issue in irradiation. To switch from their current, frozen, or non-irradiated alternatives, consumers need to see an advantage to irradiated food, such as a longer shelf life, a cleaner product, improved product characteristics, or a lower price.

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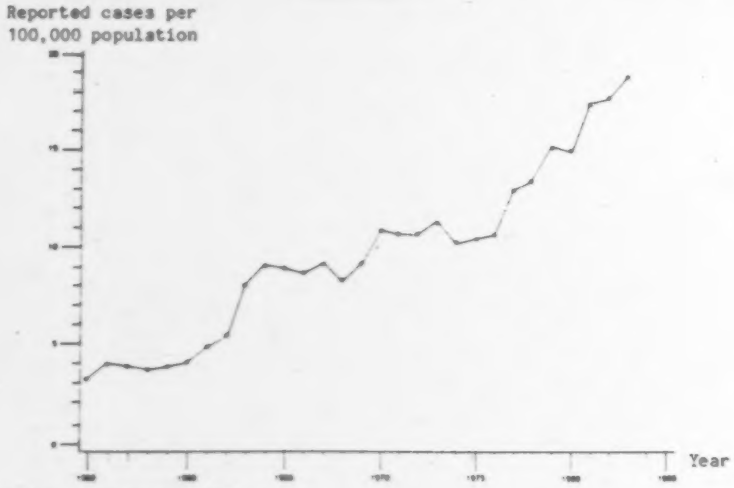
IV. POTENTIAL PUBLIC HEALTH BENEFITS OF IRRADIATING FRESH CHICKEN, PORK AND BEEF

The potential benefits of food irradiation--increased shelf life/reduced spoilage, improved quality, alternative quarantine treatments, and public health improvement--are difficult to quantify. This section estimates the potential public health protection benefits of irradiating raw chicken, pork and beef to reduce the incidence of five diseases--trichinosis, beef tapeworm, salmonellosis, campylobacteriosis and toxoplasmosis. These five diseases were arbitrarily picked and consequently the public health benefits estimated are conservative since other pathogens are ignored. Irradiation is only one of the possible methods for reducing or controlling these diseases. Other control options are discussed in chapter VII.

Trends and Causes of Foodborne Illness

A ballpark estimate of foodborne illness costs in the United States is $1 to $10 billion loss annually in medical expenses and time lost from work (Todd, 1984, p. 159). Several foodborne illnessses, such as salmonellosis, are thought to be increasing in the United States and other developed countries (Kamplemacher, 1984; Sato, 1985). Reported cases of U.S. salmonellosis have doubled in the past 16 years and an estimated 2 million cases occur annually (figure IV-1) (CDC, 1984). Other foodborne diseases, caused by Clostridium perfringens, Toxoplasma gondii, and Campylobacter jejuni, have also been increasing, and the latter is thought to be even more prevalent than salmonellosis (Holmberg, 1985).

Figure IV-1. Reported Human Salmonellosis Isolations, United States, 1955-83

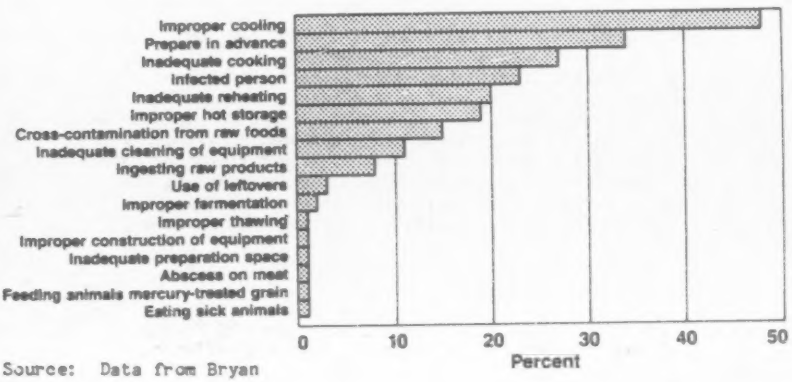


Source: Wasserman, 1985, p. 25.

The causes of this increasing incidence of foodborne disease are diverse. Some of the contributing factors include: greater concentration of animals in larger production units which permits easier transmission of disease from one animal to the other. The considerable geographic movement of animals and birds can spread disease across the countryside. Today the use of improperly processed animal byproducts and wastes in animal feeds can introduce and perpetuate disease cycle. Concentration of animal slaughter in fewer and larger plants increases the possibilities for cross-contamination between carcasses (Schwabe, 1985, pp. 552-3; Snoyenbos, 1985). The organisms themselves have been evolving. They are adapting to modern food processing and are more able to survive (Archer, 1984). Also, they are developing resistance to human drug therapies (Holmberg, et. al., 1984).

The increased number of distribution stages and eating away from home means more mass production of food and the greater inherent possibilities of improper heating and refrigeration. A CDC study of factors contributing to outbreaks of meat and poultry-borne disease found that improper cooling of food occurred in about half the outbreaks (figure IV-2) (Bryan). Cooking far in advance of eating contributed to one-third of the outbreaks. Inadequate cooking contributed to one-fourth while inadequate reheating or improper hot storage each contributed to about one-fifth of the outbreaks. If the raw meat and poultry had not been contaminated, this improper heating and cooking would not have led to foodborne disease. The 20 percent of the meals consumed outside the home (Consumers, 1985) were associated with 68 percent of the foodborne disease outbreaks reported in 1981 (CDC, 1983). Conversely, the 80 percent of the meals consumed at home caused only 32 percent of the reported foodborne outbreaks. But this may be an unfair inference because of the severe underreporting of all foodborne disease and perhaps the greater likelihood that food poisoning at home will go unreported, undiagnosed, or misdiagnosed.

Figure IV-2. Factors Contributing to Outbreaks of Meat and Poultry-Borne Diseases, United States, 1968-77



Source: Data from Bryan

IV-3

Methodology

The economic consequences of foodborne disease follow a long chain of events from exposure to medical treatment (figure IV-3). The incidence and severity of illness depends upon the number of organisms or amount of toxin encountered and in what foods, the pathogenicity of the organism or toxin, and the strength of the individual's immune system in defending against the pathogenic agents. The economic costs of the illness include the medical treatment costs, value of time lost from work or play, psychic costs, etc.

Cost Categories

Foodborne disease costs can be classified into 3 categories: individual, industry and public (table IV-1). The individual's costs associated with illness and death include medical resources used, loss of wages or productivity during sickness, reduction of leisure time choices during the illness and recovery, and pain and suffering. The costs to the industry or firm found responsible for the outbreak may include the value of product recalled, reduction in future demand for the product due to reputation damage, plant cleanup, and liability awards. 1/ Public costs include investigation, surveillance and possibly part of the cleanup expense.

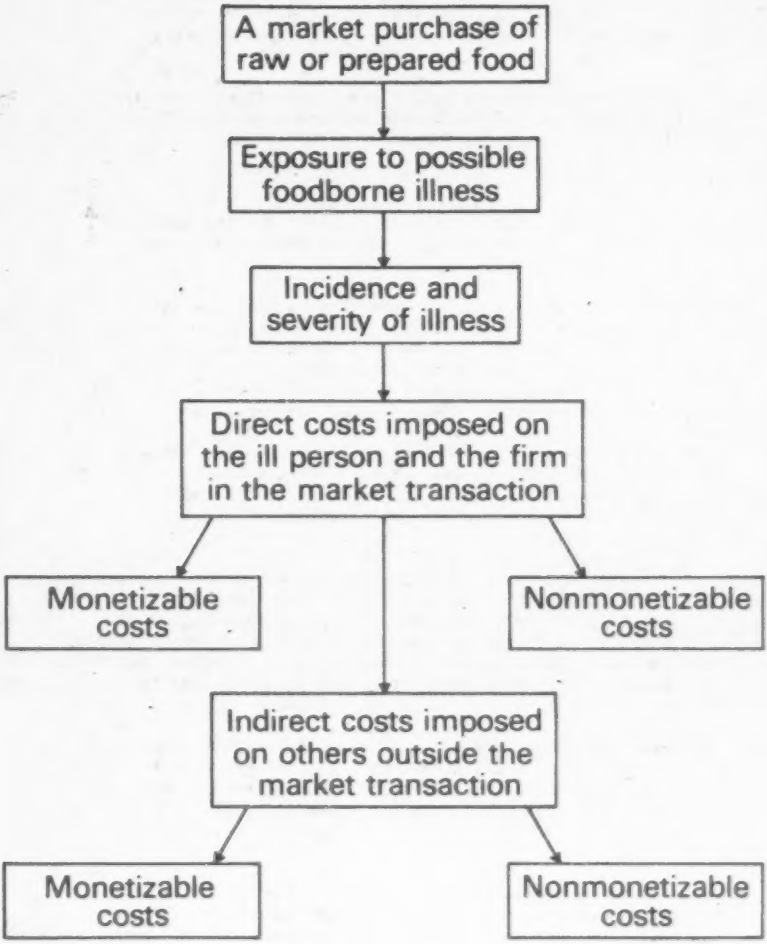
Table IV-1. Social Costs of Foodborne Illness

Costs to Individuals	Industry Costs
Medical costs	Product recall
Income or productivity loss	Plant closings and cleanup
Pain and suffering	Product liability costs
Leisure time cost	Reduced product demand
Averting behavior costs	
Risk aversion costs	Public Health Surveillance Costs
Travel costs	Costs of maintaining disease surveillance
Child care costs	Costs of investigating outbreak
	Costs of cleanup

Traditionally, only the easily monetizable, direct costs have been estimated, namely the medical costs and wages (or productivity) lost during an illness. However, averting behavior costs (behavior designed to avoid or reduce the risk of illness) can be a significant cost item and, in fact, may swamp the traditional medical and productivity costs. A recent Resources for the Future study of the contamination of a water supply found the public will pursue a variety of measures to avoid illness--boiling water, travelling to another community to obtain water, and purchasing bottled water (Harrington, et. al., 1985).

1/ In adding up costs, care must be taken to assure that product liability costs to firms are not already counted in the estimated pain and suffering cost to individuals.

Figure IV-3. Direct and Indirect Foodborne Illness Costs


A market purchase of raw or prepared food
Exposure to possible foodborne illness
Incidence and severity of illness
Direct costs imposed on the ill person and the firm in the market transaction
Monetizable costs
Nonmonetizable costs
Indirect costs imposed on others outside the market transaction
Monetizable costs
Nonmonetizable costs

Averting behavior by the public can result in diet and consumption expenditure changes that affect sales and revenues of the involved industry. An opinion survey by the National Pork Producers Council found that 40 percent of the surveyed consumers claimed that they had reduced their consumption of pork because of health concerns about salt and 17 percent claimed decreased poultry consumption because of disease concerns (Weise Research Associates, 1984). Of course, opinion surveys by themselves do not provide empirical evidence of actual reductions in consumption and impacts upon industry revenues.

Finally, the costs to firms and the public are typically excluded from cost estimates, although Ewen Todd of Health and Welfare Canada has found they are often significant components of foodborne outbreak costs.

Evaluation of Costs of Illness

The three components of the cost of illness estimate are the number of persons affected, the severity of the illness, and the costs associated with that severity:

o Estimated Disease Incidence. All diseases are typically underreported. Foodborne diseases are even more likely to be underreported because the reporting by physicians is voluntary, often the cases are mild and of limited duration so physicians may not be seen, the suspect food is seldom available to be tested for pathogens, and many foodborne pathogens have only recently been recognized and are not routinely tested (Archer, 1984, p. 321). Epidemiologists estimate the actual incidence of foodborne illness by door-to-door surveys during outbreaks to see how many persons were ill and who consulted a physician and reported the case. For example, epidemiologists have found that only 1 in 75 salmonellosis cases are reported (Smith and Blaser, 1985). Rather than just rely on reported cases, estimates of the total U.S. incidence are used whenever possible.

o Severity of Illness. The range of illnesses caused by the diseases considered here vary from essentially unnoticeable to life-threatening. Among other things, the impact depends on the number of microbes ingested and on the efficiency of the individual's immune system in fighting off the diseases. However, fatalities can occur in relatively normal human adult hosts (Smith and Blaser, 1985). Costs have been estimated for three disease severity levels--mild, moderate, and deadly.

o Cost of Illness. Secondary data sources (updated to 1985 prices) are used for the cost estimates. Often these costs are derived from surveys of people involved in an outbreak of foodborne disease. Generally, they are confined to medical costs and wage losses and are underestimates.

Evaluation of Death

Traditionally, deaths have been evaluated by the human capital method which measures the individual's contribution to productive output. The income stream that would have been produced by the individual is collapsed into a present value for that production at today's prices.

$$\text{Human Capital Method} = \sum_{t}^{T} \frac{L_t + H_t}{(1+i)^t}, \text{ where}$$

T = remaining lifetime
t = a particular year
L_t = labor income
H_t = value of nonmarket time spent on homemaking services
i = social discount rate; opportunity cost of society investing in life-saving programs

The human capital method only places a value on what the individual produces for society.

From the perspective of the individual and consumer demand theory, a life ought to be valued by what the individual is willing to pay to avoid a particular risk of death. The individual's non-labor sources of income are included as resources to pay for risk reduction along with wages. Even more important are the nonmarket activities that may be of more value to the individual than his/her income loss. These include pain and suffering, loss of leisure time, and aversion to risk.

$$\text{Revealed Preference Willingness to Pay Method} = \left[\sum_{t}^{T} \frac{B_t}{(1+\rho)^t} \right] \alpha, \text{ where}$$

T = remaining lifetime
t = a particular year
B_t = benefits of living = $L_t + NL_t + NM_t + P_t$, where L_t = labor income, NL_t = nonlabor income, NM_t = nonmarket activities and leisure, P_t = premium for pain and suffering
ρ = individual rate of time preference
α = risk aversion factor

Historically, the range of value of life of estimates resulting from the willingness to pay method has been large (Landefeld and Seskin, 1982). The Environmental Protection Agency has concluded that new willingenss to pay studies show a value of life of $1 million to $7.5 million (Benefits Branch, 1985).

A hybrid approach attempts to bridge the gap between the two methodologies (Landefeld and Seskin, 1982). The adjusted willingness to pay/human capital approach includes only measurable economic losses associated with death. It is based on after-tax income from labor and nonlabor sources, discounts at the individual's rate of return after taxes, and includes risk aversion shown by investment in life insurance, security systems, etc.

$$\text{Adjusted Willingness to Pay/Human Capital Method} = \left[\sum_{t}^{T} \frac{Y_t}{(1+r)^t} \right] \alpha, \text{ where}$$

T = remaining lifetime
t = a particular year
Y_t = after-tax income = $L_t + NL_t$, where L_t = labor income, NL_t = nonlabor income
r = individual's opportunity cost of investing in risk-reducing activities
α = risk aversion factor

Perhaps most important, pretty good data exist for estimating with this methodology.

The Cost of Selected Foodborne Diseases

Two diseases associated with chicken consumption, two with pork and two with beef are described and evaluated. The illness costs are medical expenditures and lost productivity. Deaths are evaluated with the two methodologies described above.

Salmonellosis

Typically, Salmonella-caused disease is limited to salmonellosis, an acute gastroenteritis which appears 12 to 74 hours after eating contaminated food. Salmonellosis may cause only mild abdominal discomfort with minimal diarrhea lasting less than a day. More acute symptoms of disease include nausea, stomach ache, vomiting, diarrhea, cold chills, fever, and exhaustion. The symptoms of disease normally persist for 2 to 6 days, but in exceptional cases for several weeks. A small percentage (0.1 percent) of the people who contract salmonellosis die from it, and fatality is generally limited to the sick, those taking antibiotics, infants, or the elderly. However, in rare cases Salmonella, like some other bacterial and parasitic infections, can cause chronic disease syndromes (see table IV-A).

There are over 2,500 different Salmonella serotypes, "all of which should be considered as potentially pathogenic to man" (Orskov and Orskov, 1982, p. 345). The number of organisms needed to cause disease varies, partly depending on the virulence of the specific organism and partly depending on the body defences mounted by the recipient. However as few as 10 cells of Salmonella per gram or per milliliter in hamburgers and pasteurized milk have been reported to cause disease (Hulder, 1982, p. 8). Pepper, chocolate, cider, and watermelon are other diverse foods which are rarely the source of salmonellosis.

Salmonella organisms are very resourceful and adaptive. They have the capacity to parasitize a multitude of hosts, including mammals, birds, reptiles, and insects. They may hide in cells to avoid many of the body's defense mechansms. Although they do not form spores, certain strains of Salmonella are relatively resistant to drying, freezing, and dry heat. These factors account for their successful adaptation and for the significant advantages they have in the host-parasite balance (Cohen and Gangerosa, 1978, p. 1542).

"The enormous reservior of contaminated food products, especially poultry products, has caused steady increase in the incidence of salmonellosis" (Berkow, 1982, p. 103). In an examination of U.S. poultry from eight retail markets, 50.2 percent of 237 dressed chickens were Salmonella positive in

1966 (Wilder and MacCreedy, 1966, p. 1453). In 1980, the Food Safety and Quality Service (FSQS) of USDA reported a 37 percent incidence of Salmonella in 600 ready-to-market chickens sampled in 15 processing plants in 11 states (Food Chem. News, Feb. 25, 1980, p. 12).

Historically, poultry has been the most important vehicle of salmonellosis reported to the U.S. Centers for Disease Control (CDC), with turkey causing the bulk of the outbreaks (Cohen and Blake, 1977, p. 799). Recently rare roast beef has become an important cause. In 1981 beef caused 9.5 percent (Salmonellosis Surveillance, 1983). Given the estimate of 2 million cases annually of salmonellosis by the Carter Center for CDC/Emory University (Holmberg, 1985), beef and chicken can be estimated to be the direct cause of 620,000 and 190,000 cases, respectively, of salmonellosis annually in the United States. (Turkey is not examined here because of its greater sensitivity to irradiation and the development of off-flavors (table II-1).

The most extensive data on costs come from a CDC investigation of the Colorado outbreak (Cohen, et. al., 1978). The average survey respondent reported costs of $1,290 (in March 1985 $)--medical costs of $938, wage or productivity losses of $289 and miscellaneous costs of $62 (table IV-2).

Table IV-2. Patient-related Costs Associated with Salmonellosis

Cost Categories	Average Cost Per Person[a/]	
	1976 Prices	Updated to Mar 85 prices
	dollars	dollars
Medical costs, total	441.88	938 [b/]
Physician office fee	39.03	
Emergency room	16.88	
Medication	9.56	
Hospitalization	376.41	
Income or productivity loss	170.24	289 [c/]
Miscellaneous	33.71	62 [d/]
Total	$645.83	$1,290 [e/]

a/ Not all persons incurred costs in each category, thus the average costs are below those actually incurred by an individual since costs are averaged over the total number of cases.
b/ Updated using the medical cost component of the Consumer Price Index (CPI) for February 1985 vs. 1976.
c/ Updated using the average weekly earnings for March 1985 vs. 1976.
d/ Miscellaneous costs include transportation, child care, other laboratory tests, finding new jobs. The 1985 value is updated using the all items CPI value for 1976 vs. March 1985.
e/ The total is rounded to the nearest $10.
Source: Cohen, et. al., 1978, for 1976 cost. 1985 update provided by author.

The reported cases in this outbreak are assumed to be representative of all cases reported to CDC. There are roughly 40,000 salmonellosis cases reported annually (Holmberg, 1985).

For those 2,000 salmonellosis patients who are estimated to die, the present value of life is calculated by two methods. The low estimate uses the very conservative, and perhaps antiquated, human capital method. When the actual age and sex distribution of reported salmonellosis deaths is combined with the present value of income and homemaking services, the average life is estimated at $85,800 (table IV-3). The high estimate uses the more generous (but still an underestimate) adjusted willingness to pay/human capital method. Combined with the actual reported age and sex distribution of salmonellosis deaths this results in a value of life of $351,500.

Mild cases of salmonellosis are the remainder of the estimated 2 million cases minus the 40,000 reported cases, or 1,960,000 cases. Costs are not well studied. Some of the unreported cases are as serious as the reported cases, but the bulk are probably much less severe. How much less severe is not known now, but a current survey of the Illinios milk outbreak in the spring of 1985 will provide data in the near future. Until then the mild

Table IV-3. Present Value of Life for Salmonellosis Fatalities, 1985

Method	Age	Male			Female			Average Value 3/
		Deaths	Present Value	Total Value	Deaths	Present Value	Total Value	
		number	thousand dollars		number	thousand dollars		dollars
Human capital 1/	0-4	3	88	264	4	77	307	
	5-15	0	159	0	2	139	278	
	15-24	2	300	600	1	241	241	
	25-44	0	371	0	4	238	954	
	45-64	10	189	1,890	6	144	867	
	65+	20	14	271	27	41	1,107	
		35		3,025	44		3,754	85,800
Adjusted willingness to pay/human capital 2/	0-4	3	1208	3,624	4	836	3,102	
	5-14	0	1408	0	2	961	1,922	
	15-24	2	1655	3,309	1	1086	1,086	
	25-44	0	1432	0	4	866	3,462	
	45-64	10	548	5,480	6	410	2,458	
	65+	20	34	680	27	90	2,443	
		35		13,581	44		14,675	351,500

1/ Data from Dolan, et. al., 1980; Vital, 1984; Updated to March 1985 dollars.
2/ Data from Landefeld and Seskin, 1982; Vital, 1984; Updated to March 1985 dollars.
3/ Value calculated by dividing the total values for male and female by total number of deaths.

[illegible]

Table [illegible]. U.S Costs for Salmonellosis, 1985.

Cost Categories	Costs per case	Cases	Total
	dollars	number	$ 1,000,000 dollars
Medical Costs			
Mild cases	0	1,663,000	0
Moderate cases and deaths	[illegible]	[illegible]	[illegible]
Lost Productivity			
Mild cases	[illegible] a/	1,663,000	[illegible]
Moderate cases	[illegible] a/	[illegible]	[illegible]
Deaths:			
Human capital method	[illegible]		[illegible]
or	or	[illegible]	or
Adjusted human capital/willingness to pay method	[illegible]		[illegible]
Miscellaneous costs b/	[illegible]	[illegible]	[illegible]
Total		[illegible] to [illegible] million	

a/ Miscellaneous costs include transportation, child care, other laboratory tests, finding new jobs.
b/ This productivity loss estimate for mild cases also includes some miscellaneous costs of undetermined amount.
c/ This is a low estimate because it ignores not the value of homemaking.

cases are assumed to have costs of $[illegible] apiece (March 1985 $) which is what [illegible] estimated for an unreported case of salmonellosis in the Pittsburgh outbreak. 2/

The medical costs and lost productivity for 2 million salmonellosis cases in the United States total an estimated $[illegible] million to $[illegible] million annually for the mild cases, moderate cases and deaths (Table [illegible]). If children is responsible for 6.5 percent of these cases as the 1985 CDC data suggests, then the children related losses are $[illegible] to $[illegible] million annually. If beef causes 21 percent of the cases of salmonellosis as also suggested by the 1985 CDC reported outbreaks, then the beef associated losses are $[illegible] to $[illegible] million annually.

1/ The $[illegible] figure reported in the original article is updated using the change in the Consumer Price Index.

[illegible]

[illegible]

[illegible]

[illegible]

Table [illegible]. U.S. Costs for [illegible], 1985

Cost Categories	Costs per case	Cases	Total Estimate Low	Total Estimate High
	dollars	number	1,000,000 dollars	
Medical Costs				
Mild Cases	0	3,040,000 or 1,827,875	0	0
Moderate Cases and Deaths	838	97,200 or 108,035	53.8	121.6
Lost Productivity				
Mild Cases	738 1/	3,041,000 or 1,827,875	1824.8	1644.4
Moderate Cases	280 1/	97,200 or 108,035	18.2	68.3
Deaths: Human capital method or Willingness to pay	85,800 or 211,000	2,700	181.2	726.2
Miscellaneous 2/	62	97,200 or 108,035	3.8	13.4
Total		8753	to 87,359 million	

1/ Productivities costs include transportation, child care, other laboratory tests, finding a new job.
2/ Mild productivity loss estimate for mild cases also includes some intermittent costs of moderate cases.
3/ Note it is the discounted variable in summary not the value of homemaking.

A human infective dose can be as few as 500 Campylobacter organisms (Gilbert, 1981, p. 94). The laboratory tests to identify the pathogen have been perfected in the last decade, consequently the testing and reporting for campylobacteriosis is minimal. Surveys in Denver and Seattle, however, give us two estimates of the number of cases of moderate illness (Smith and Blaser, 1985; Seattle, 1984). Extrapolating to the United States, the Denver study suggests 57,280 moderate cases annually nationwide and the Seattle study 144,875 moderate cases (table 19-5).

The mild cases are the residual between the 2.1 million annual cases of campylobacteriosis and the low and high estimate for the moderate cases. Like salmonellosis, the case-fatality rate is 1,000 to 1, for an estimated 2,100 fatalities a year.

The medical and productivity costs associated with campylobacteriosis are estimated at between $700 million to $1.4 billion annually. Note that the productivity costs dominate and are important for both illnesses and deaths (table 19-5).

Most commercially raised poultry have C. jejuni in their intestinal flora and intestinal spillage during processing is considered to be the route of contamination (Seattle, 1984, p.8; Blaser, 1984, p. 58; Doyle, 1981, p. 68). Chicken was associated with about half of all cases of campylobacteriosis in the Seattle study (1984, p. 3), the only comprehensive U.S. campylobacteriosis surveillance study. If chicken is also responsible for half the campylobacteriosis cases in the whole United States, then the chicken related medical and productivity costs of campylobacteriosis are roughly $350 to $700 million annually.

Trichinosis

Some hog producers are supporters of irradiation for eradication of trichinosis and the FDA has just approved irradiation of 30 to 100 krads for this purpose (50 FR 20008-010). The decline in human cases of trichinosis has been dramatic in the U.S., while in Germany the disease has all but disappeared, largely because they inspect for it (Pavlowski, 1981). Trichinosis varies from asymptomatic illness to death depending largely on the numbers of live larvae ingested which have not been killed by cooking. After offspring are produced in the small intestine, they migrate throughout the body, lodge in the muscles, and may produce a wide variety of ailments. Consequently many cases of trichinosis are undiagnosed because they are so mild or misdiagnosed because of the diversity of symptoms (Zimmerman, Steele and Regan, 1971). Autopsy data indicates there maybe 100,000 exposures annually (Carter Center, 1981). Most of these cases are successfully fought off by the individual's immune system without causing illness in the individual.

Reported cases of trichinosis averaged 152 human cases annually from 1975-81 (Roberts, 1983). Pork and ground beef contaminated with pork were responsible for roughly 80 percent of the reported cases, or 121 cases (Richards, Roberts and Chisholm, 1984, p. 2555; Roberts, 1983).

To estimate the unreported cases, there is information from an outbreak occurring at sea. Three cases of trichinosis were reported while 10 other cases were found in the follow-up epidemiological investigation (Singal, Schantz, and Werner, 1976). If this outbreak is representative, then there are 3.3 unreported cases for each reported case of trichinosis (10/3). The estimated number of unreported cases of trichinosis caused by pork is 432 annually (131 reported cases x 3.3). The pork-caused total becomes an estimated 563 cases annually (131 reported + 432 unreported).

Medical costs and lost wages were estimated for an outbreak of trichinosis affecting seventeen people in 1975 (Potter et. al. 1976). In 1985 prices the per patient cost was $2,485 (table IV-6). Using these costs for the estimated 563 cases results in $1.4 million cost per year for pork-related cases of trichinosis.

Table IV-6. Average Medical Costs and Lost Wages for Seventeen Trichinosis Patients, 1975, Updated to 1985 Prices

Costs	1975 a/	1985 b/
	----------dollars----------	
Medical care, total	801	1,860
hospital costs	696	
drugs	15	
office calls	90	
Wages lost	344	625
Total	$1,145	$2,485

a/ Source: Morris E. Potter, Mary B. Kruse, Muriel A. Matthews, Raymond O. Hill and Russell J. Martin "A Sausage Associated Outbreak of Trichinosis in Illinois" American Journal of Public Health Vol. 66, No. 12 (1976) pp. 1194-96. The costs for one patient were not broken down in the original source and these have been allocated to the categories by the present breakdown in the other cases.
b/ Medical care updated to February 1985 $ using the medical cost component of the Consumer Price Index. The wages lost updated to March 1985 $ using the average weekly earnings reported by the Bureau of Labor Statistics.

Also, about one death a year is reported for trichinosis. For the high estimate I assumed that deaths are underreported just like illnesses and that pork would cause roughly three deaths a year. 1/ Combining the actual age and sex distribution of deaths reported for helminthioses (trichinae and related

1/ While death certificates list the cause of death, the variety of organs affected by trichinosis make the diagnosis difficult unless an autopsy is performed.

worm-like parasites) (Vital, 1984) with the two methods for evaluating life results in a low and a high estimate. The high estimate uses three deaths and the adjusted human capital/willingness-to-pay evaluation of $471,000 a piece for a total of $1.4 million (table IV-7). For the low estimate the human capital method of evaluating deaths due to helminthiases yields $140,000 per death and only the one reported death is counted. Thus the deaths add $0.1 to 1.4 million to the estimated annual cost of trichinosis in the U.S. This gives a total cost range illness for and deaths due to trichinosis of $1.5 to 2.8 million (table IV-10).

Table IV-7. Present Value of Life for Deaths Caused by Helminthiases

Method	Age	Male			Female			Average value
		Deaths	Present Value	Sum	Deaths	Present Value	Sum	
		number	1,000 dollars		number	1,000 dollars		dollars
Human Capital	0-4	0	87	0	0	76	0	
	5-14	0	158	0	0	138	0	
	15-24	0	299	0	0	239	0	
	25-44	4	369	1,476	2	237	474	
	45-64	6	188	1,128	0	144	0	
	65+	8	13	104	4	41	164	
				$2,708			$638	$140,000
Adjusted human capital/ willingness to pay 2/	0-4	0	1,202	0	0	821	0	
	5-14	0	1,401	0	0	956	0	
	15-24	0	1,646	0	0	1,080	0	
	25-44	4	1,425	5,700	2	861	1,722	
	45-64	6	545	3,270	0	408	0	
	65+	8	32	256	4	90	360	
				$9,226			$2,082	$471,000

1/ Data from Dolan, et. al., 1980; Vital, 1984; Updated to February 1985 dollars.
2/ Data from Landefeld and Seskin, 1982; Vital, 1985; Updated to February 1985 dollars.
3/ Value calculated by dividing the total values for male and female by total number of deaths.

Toxoplasmosis

Another disease arising from consuming undercooked pork, or in rare instances handling of raw pork, is toxoplasmosis. There are only two environmental sources of infection--meat and ingesting soil contaminated with cat feces. Pork and mutton are commonly infected in the U.S. whereas beef or broilers are rarely infected (Jacobs, Remington and Melton, 1960; Ruiz and Frenkel, 1980). Dubey, et. al. (1979) report that several surveys show widespread, asymptomatic infections with Toxoplasma gondii in U.S. pigs. There are no concrete numbers on the sources of toxoplasmosis, but public

health researchers suggest that pork causes half to three quarters of the U.S. cases. 4/

An exposed person's immune system typically responds, fights off toxoplasmosis, and leaves antibodies in the blood. By taking blood samples, the age distribution of exposure to toxoplasmosis can be determined. In the U.S., adults are most exposed due to the post-adolescent cultural habit of eating undercooked or raw meat.

Toxoplasmosis causes three other types of disease syndromes in adults. A common infection of the lymph system; the occasional, more severe infection of the lymph system plus another organ such as the brain, heart, lung, liver or skeletal muscles; and finally a rare life threatening, generalized toxoplasmosis which is usually associated with immunological deficiency. 5/ Most cases of toxoplasmosis are mild and fought off by our immune system. However, an estimated 2.3 million cases occurr annually. The benefit of preventing these adult cases is likely to be substantial, but impossible to quantify at this time.

If a pregnant woman becomes infected with toxoplasmosis there is a 20-40 percent probability her fetus will be infected. Surviving babies are likely to suffer eye damage and have a probability of mental retardation. An estimated 3,300 babies born every year in the U.S. are infected. Wilson and Remington conservatively estimated the life time cost for 3,300 children born with congenital toxoplasmosis in the U.S. every year was $430 million each year (updated to 1985 prices in table IV-8). Because babies born every year are exposed to the risk of toxoplasmosis, in a steady state with a constant number of births each year, the annual costs incurred would be $430 million each year. 6/ Then, the cost of mental retardation and eye problems in babies due to the 50-75 percent of cases caused by pork is estimated at $215 to $323 million annually.

4/ Kenneth Walls, Protozoan Disease Branch, CDC suggested 50 percent and Jacob Frenkel, University of Kansas Medical Center, suggested 75 percent (personal communications, 1985). Also, Dubey, Murrell and Fayer report that "ingestion of cysts in undercooked pork infected with Toxoplasma gondii is thought to be a major source of Toxoplasma infection in human beings" (1984, p. 1941). They also report that Toxoplasma gondii can persist in the edible tissue of pigs until slaughter.

5/ Once exposed to toxoplasmosis, the individual is likely to be left with cysts embedded in tissue for the rest of his/her life. If the individual's immune system fails because of old age, immunosuppressive diseases such as cancer, immunosuppressive drug, or if the cysts are mechanically broken, an acute phase of the infection begins again (Fayer and Dubey, 1985, p. 57).

6/ This estimate is conservative because it does not include pain and suffering for the babies born with a mental or visual handicap and the suffering of the parents of these babies or the 15 percent who died. In addition, the survivors' medical complications have been underestimated and no adjustment has been made for reduced earning capacity caused by toxoplasmosis. Finally, the income losses due to parents caring for the child instead of working are not included.

Table IV-8. Lifetime Cost for Special Services for 3,300 Children with Congenital Toxoplasmosis Born in the United States Each Year, 1985

Service Required	Utilization	Cost of Service
	percentage	1,000,000 dollars
Yearly ophthalmologic follow-up care	78.0	4
Special schooling for visually handicapped	14.2	68
Special schooling for moderately retarded	7.1	23
Institutional or state-supported foster care for severely retarded	15.1	301
Aid to totally disabled	2.4	33
Total		$430 million

Source: Wilson and Remington and updated by author to 1985 $ using the Consumer Price Index.

Beef Tapeworm (Taenia saginata)

Eating a live larvae that has not been killed by thorough cooking will infect a person. Unless medical treatment is provided, the mature tapeworm will live in the intestine until the death of the individual. Symptoms vary in their intensity and some persons never realize they have a tapeworm. However most people experience symptoms which "...may include nervousness, insomnia, anorexia, loss of weight, abdominal pain, and digestive disturbances" (Benenson, 1975, p. 319). Occasionally, other organs are invaded and serious disorders can occur (Hubbert, McCullock, and Schnurrenberger, 1975, p. 679).

The Carter Center of CDC/Emory University estimates that 1,000 tapeworm cases occur annually in the U.S. Typically the disease symptoms are mild. The cost to remove a tapeworm involves two visits to a doctor, a stool examination, and drug treatment (Roberts, 1983, p. 34). These medical costs and time-off work for the visits to the doctor are estimated at $111 per case (table IV-9). The annual cost due to the beef tapeworm, Taenia saginata is estimated at $0.1 million (Table IV-9).

Table IV-9. Costs to Treat a Human with Taenia saginata (Tapeworm)

Type of Costs	Cost per Case
	dollars
Medical costs	77
Lost wages	34
Total	$111

Source: Roberts, 1983, p. 34.

Table IV-10. Public Health Costs and Wages Lost due to Disease Contracted from Meat and Poultry

Disease	low estimate	high estimate
	-----million dollars-----	
Pork		
trichinosis	1.5	2.8
congenital toxoplasmosis	215	323
Chicken		
salmonellosis	64	115
campylobacteriosis	362	699
Beef		
salmonellosis	209	374
tapeworm	0.1	0.1
TOTAL	$851.6 million	$1.5 billion

Disease Cost Summary

The medical costs and productivity losses for five foodborne diseases associated with raw chicken, pork and beef total around one billion dollars annually (table IV-10). Trichinosis and beef tapeworm are relatively minor hazards, but salmonellosis, campylobacteriosis and congenital toxoplasmosis all have impacts in the hundreds of millions of dollars each year.

Still these cost estimates omit the chronic complications that can result from all five diseases, ranging from arthritis, to blood poisoning to heart disease (Appendix IV-A). Also, a Canadian study has found that the value of leisure time lost during salmonellosis is greater than medical costs and productivity losses combined (Curtin, 1984).7/ Finally, other individual costs such as averting behavior as well as industry and public costs are omitted (Table IV-1).

7/ Thus the actual costs for salmonellosis and campylobacteriosis could be more than double the estimates presented here.

Irradiation as a Control Technique

Irradiation has been proposed as a techinque to control microbial contamination of meat and poultry. Other control options, such as cooking meat better to kill pathogens, are discussed briefly in section VII. The Codex Alimentarius Commission suggests doses up to 700 krads (7 kGy) to reduce the number of pathogenic microorganisms in chicken (Codex Alimentarius, 1984, p. 9). USDA is considering petitioning FDA to allow irradiation for microbial control ("USDA May", 1985). Some researchers hypothesize that doses as low as 100 to 200 krads (1 to 2 kGy) would still significantly reduce Salmonella and other pathogenic organisms (Kahan and Kowker, 1978, p. 236).

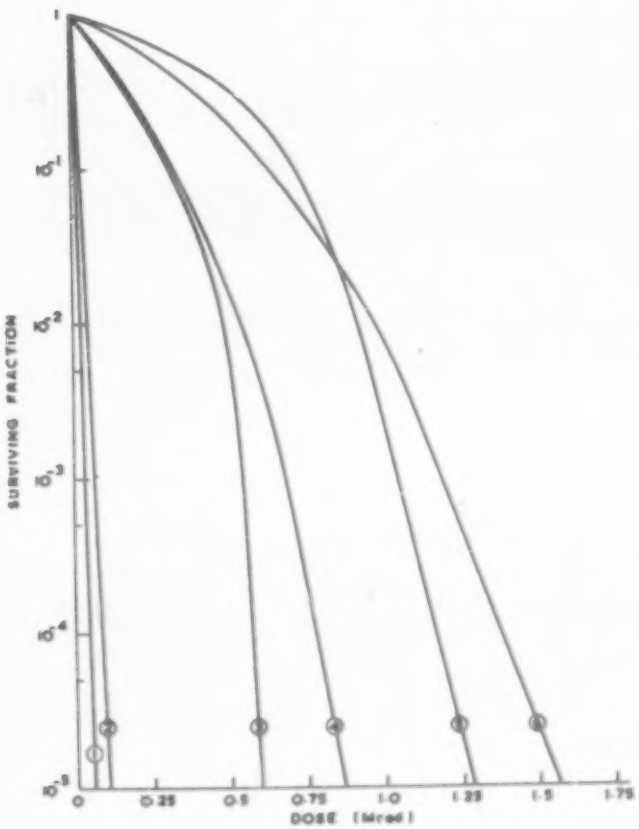
Bacteria differ greatly in their sensitivity to ionizing radiation (figure IV-5 and chapter II). Different studies on the elimination of Salmonella from poultry meat or skin have reported D_{10} values--the radiation dose necessary to reduce the bacterial population by 90 percent (or one log cycle)--from 18 to 99 krads (0.2 to 1.0 kGy), depending on the serotype and the media used (Mulder, 1982, p. 30). Researchers at the Spelderholt Institute for Poultry Research concentrated on determining the effect of the 250 krad (2.5 kGy) dose level on salmonellae and other microflora in chickens purchased through normal retail channels. The scientists also innoculated microorganisms into the chicken to increase the salmonellae load. Interestingly, there was great variance in the numbers of salmonellae isolated after radiation treatment partially depending upon where the sample came from and which media was used to grow up the samples. "The data obtained from the artificially contaminated carcasses and from the experiment in liquid culture media indicate that D_{10} values for Salmonella vary between D_{10}=[30 krad or 0.3 kGy] and D_{10}=[130 krad or 1.3 kGy]. Even duplicate tests showed substantial differences" (Mulder, 1982, p. 92).

Nonetheless, by assuming a D_{10} value of 80 krads, Mulder constructed table IV-11 showing the number of positive chicken carcasses after irradiation at 250 krads as a function of the percentage of broilers initially contaminated and the level of contamination, or number of colony forming units (cfu) of Salmonella. For example, if 25 percent of the carcasses were contaminated with 100 cfu of Salmonella per gram, after receiving a dose of 250 krads only one in 55 carcasses would remain contaminated. If 50 percent of the carcasses were initially contaminated with 100 cfu per gram, the contaminated carcass rate would fall from 50 percent to 3.6 percent (1 in 28 carcasses). Mulder generalized that radiation treatment at 250 krad causes a 93 percent reduction in Salmonella contaminated chicken carcasses (Mulder, 1982, p. 94). 8/

Maxcy concluded that a low dose of 200 krads (2 kGy) would "essentially eliminate" campylobacter (Maxcy, 1983, p. 210). Tarkowski et. al. reported a four log reduction in campylobacter in ground beef at 100 krads (1 kGy) (1984, p. 1). Irradiation of fresh chicken at 250 krads (2.5 kGy) would eliminate campylobacter.

8/ After irradiation the broiler carcasses had spoilage patterns comparable to nontreated carcasses and no new public health hazards occur (Mulder, 1982, p. 117; Firstenberg-Eden, et. al., 1983). At higher doses which kill the lactic bacteria, the potential for botulism contamination could exist (see chapter II).

Figure IV-5. Typical Dose/Survival Curves for a Number of Irradiated Bacterial Species



Note: 1. Pseudomonas sp. 2. Salmonella typhimurium. 3. Streptrococcus faecium A_21. 4. Bacillus pumilis spores. 5. Clostridium botulinum type A, spores. 6. Micrococcus radiodurans. Irradiated in buffer suspension in the presence of air.
Source: Ley, 1983, p. 119.

Table IV-11. Proportion of Carcasses Contaminated after Irradiation with 250 krads (2.50 kGy) when the D_{10} value = 80 krads (.8 kGy)

Mean of salmonellae (cfu)/gram	Percentage of broilers initially contaminated	Positive carcasses after the treatment
	percent	
5	5	1 : 5,340
	10	1 : 2,670
	25	1 : 1,070
	50	1 : 534
10	5	1 : 2,680
	10	1 : 1,340
	25	1 : 535
	50	1 : 208
100	5	1 : 277
	10	1 : 138
	25	1 : 55
	50	1 : 28

Source: Mulder, 1982, p. 92

Irradiation of split pork carcasses at 30 krads is sufficient to inactivate Trichinella spiralis and irradiation at 50 krads kills Toxoplasma gondii (King and Josephson 1983; Dubey, Brake, Murrell, and Fayer, 1985). Thus, irradiation of pork carcasses at 50 krads would be sufficient to prevent human trichinosis and toxoplasmosis associated with pork (table IV-12).

Beef causes more cases of salmonellosis than fresh chicken. It can also cause tapeworm infection which is more of a nuisance than a health hazard. Irradiation of beef at 250 krads to destroy Salmonella will also destroy beef tapeworm (Josephson and King, 1983, p. 251). In fact, as little as 40 krads will prevent development of a tapeworm in a human host (ibid).

Irradiation could significantly reduce all five foodborne illnesses. However, the costs of irradiation may be greater than the public health benefits of reducing these disease (chapter V) or other control options may be cheaper and provide more net benefits to society (chapter VII).

Table IV-12. Costs Per Case of Foodborne Illness and Irradiation Dose

Foodborne Illness	Cost per Case a/	Source of cost estimate	Irradiation Dose
	dollars		krads (kGy)
trichinosis			
illness, average	2,485	Potter, et. al.	30
death	140,000-471,000	Vital; Landefeld & Seskin; Dolan, Hodgson & Wun	(0.3)
congenital toxoplasmosis			
illness, average	130,303	Wilson & Remington	50
fetal deaths (excluded)	0		(0.5)
salmonellosis/campylobacteriosis			
mild illness	230	Cohen, et. al.	250
moderate illness	1,290	Cohen, et. al.	(2.5)
death	85,800-351,500	Vital; Landefeld & Seskin; Dolan, Hodgson & Wun	
tapeworm			
illness, average	111	Roberts	40 (0.4)

a/ Updated by author to 1985 prices.

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Appendix IV-A. Complications Observed After Bacterial and Parasitic Infections Transmitted by Foods

Infection	Complication Caused
Bacterial infections:	
Salmonellosis	cholecystitis, colitis, endocarditis, meningitis, thyroiditis, myocarditis, rheumatoid syndromes, Reiter's disease, splenic abscesses, septicaemia, pancreatitis, osteomyelitis, aortitis
Yersiniosis	arthritis, erythema nodosum, spondylitis, septicaemia, liver and splenic abscesses, cholangitis pneumonia, lymphadenitis
Shigellosis	septicaemia, splenic abscesses, haemolytic-uraemic syndrome, synovitis
Campylobacteriosis	cholecystitis, colitis, endocarditis, meningitis, arthritis, carditis, septicaemia, erythema nodosum
V. parahaemolyticus-enteritis	septicaemia
Q-fever	endocarditis
Parasitic infections:	
Giardiasis	dystrophy, lymphoidal hyperplasia, joint symptoms
Taeniasis	arthritis
Toxoplasmosis	pancarditis, central nervous system disease
Trichinosis	neurological sequelae, cardiac dysfunction

Source: Mossel, 1984, p. 93.

V. IRRADIATION COST ESTIMATES AND ECONOMIES OF SCALE

Before any process will be used, prospective users must believe that it is economically feasible. Economic feasibility implies that the costs of the treatment are equal to, or preferably less than, the benefits. Also, processors or consumers must value the benefits enough to pay the additional cost. Irradiation must compete with alternative treatments and achieve the same effect at a lower price or with fewer drawbacks (i.e., no harmful residues). Often, a new process must have superior qualities or significantly lower costs for processors to abandon existing equipment and handling procedures.

The beginning point in answering the question of irradiation's economic feasibility is to determine the cost of the process. This information can then be compared with the value of the benefits irradiation offers, as well as the cost of substitute processes, to make a judgement on its economic feasibility. The estimates in this chapter are for the treatment cost alone. They do not include transportation charges for getting product to a centralized facility or the potential costs of disruptions or delays in marketing, a possible educational campaign to acquaint consumers with irradiation, research and development monies, and other costs the firm may incur.

The treatment costs are approximations because of the generalized nature of this analysis. These estimates are meant to provide an idea of the magnitude of irradiation treatment costs. The actual cost of irradiating a specific food will depend on the required radiation dose, the food's tolerance to radiation, construction costs, land prices and necessary site preparation, wage levels, financing arrangements, and many other variables. If commercial experience with irradiating food grows, more exact cost information should become available allowing these estimates to be refined.

The Economic Research Service decided to examine irradiation costs in terms of plant economies of scale. Economies of scale refer to the relationship between total average costs per unit of output (unit costs) and the size of the plant. Economies of scale exist if unit costs fall as size increases. Processes that are capital intensive--where costs for equipment and raw materials dominate labor costs--usually demonstrate economies of scale.

The existence of economies of scale has important implications for adoption patterns of a technology and industry structure. If the economies of scale are substantial, owners of small irradiators would be at a distinct cost disadvantage when faced with direct competition from large low-cost firms. Substantial economies of scale could also discourage an industry of small, widely-scattered agricultural firms from using the technology.

The following analysis examines the economies of scale for five cobalt-60 irradiators, each treating a different food product. The purpose of this research was to identify the key cost components in building and operating a commercial size cobalt-60 irradiator and to illustrate how unit costs vary with the type of application or dose level, the size of operation, and capacity utilization.

Cobalt-60 was selected as the radiation source for several reasons. One of the assumptions in setting up the model irradiators was that four of the five foods are irradiated in their packaged form in shipping boxes or crates. Penetrating gamma rays emitted from radioisotopes, like cobalt-60 and cesium-137, or X-rays from a machine source must be used to irradiate boxed products.[1/] Up to this time, there has been no commercial use of cesium-137, whereas cobalt-60 has been used for sterilization of medical supplies in the United States since the mid 1960's. Cobalt-60 is used in several facilities irradiating foods in Europe and South Africa (see chapter on international situation).

Costs were estimated for single purpose irradiators to illustrate the lower costs possible with an in-house facility dedicated to treating one product for a specific purpose. Another approach would be to irradiate foods in a multi-purpose irradiator similar to some of the commercial contract sterilizers operating today.[2/] However, the flexibility needed to handle diverse products receiving different doses sacrifices efficiency and increases costs (Dietz, 1983, p. 7). The author decided to examine costs for single purpose food irradiators.

Major Components of a Cobalt-60 Irradiator

The design and components of irradiators are discussed in detail in several studies (Chu, 1976; Bradburne, 1972; Brynojolfsson, 1972). The following paragraphs discuss the major cost components included in this analysis (see figures V-1 and V-2).

Radiation Source

The central component of an irradiation facility is the radiation source. The amount of cobalt-60 needed depends on the amount of product to be treated per unit of time, the dose required to achieve the desired effect, and the net utilization efficiency of the cobalt-60 (Brynjolfsson, 1972, p. 19).[3/] Net utilization efficiency is the percent of energy emitted by the source that is absorbed in the product.[4/] The formula for determining the approximate number of curies needed is given in Appendix V-A. Increasing the treatment rate or the dose required raises the source needs. Conversely, holding other

1/ High energy electrons from a machine source, with a maximum penetration depth of 3 inches, are not powerful enough to treat boxed products. Rather they are likely to be used for surface treatments of foods or penetration of a thin stream of products, such as grain, cocoa powder, and poultry feed (see next chapter).

2/ Care must be taken to assure that pathogens are not transferred to a commodity scheduled for low dose treatment.

3/ Cobalt-60 quantities are usually measured in curies. One curie equals 3.7×10^{10} disintegrations per second (Goresline, 1970, p. 5). Dose levels are usually discussed in terms of rads (radiation absorbed dose) or grays as defined in footnote 1 of chapter II.

4/ Not all the energy emitted by the source is absorbed in the material being irradiated. Radiation is also absorbed by the source itself and the conveyors; some radiation travels in between the product; and some radiation passes through the product into the walls.

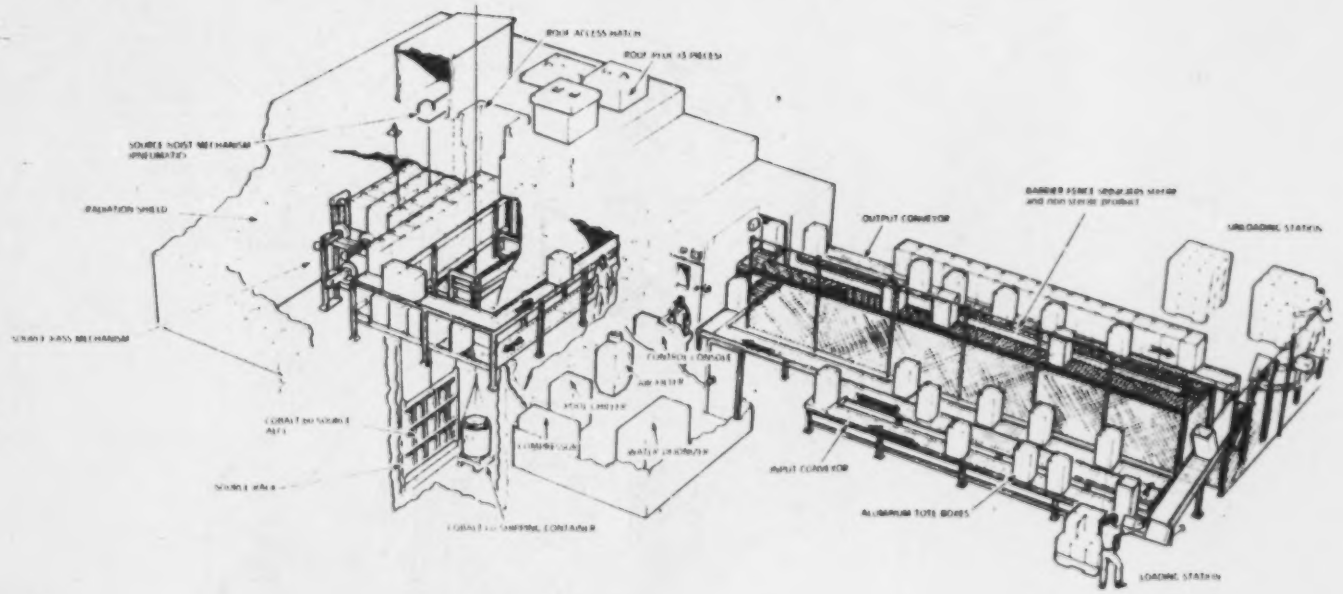

Figure V-1. Drawing of an Automatic Tote Box Irradiator (Courtesy of Atomic Energy of Canada, Ltd., Ottawa, Canada).

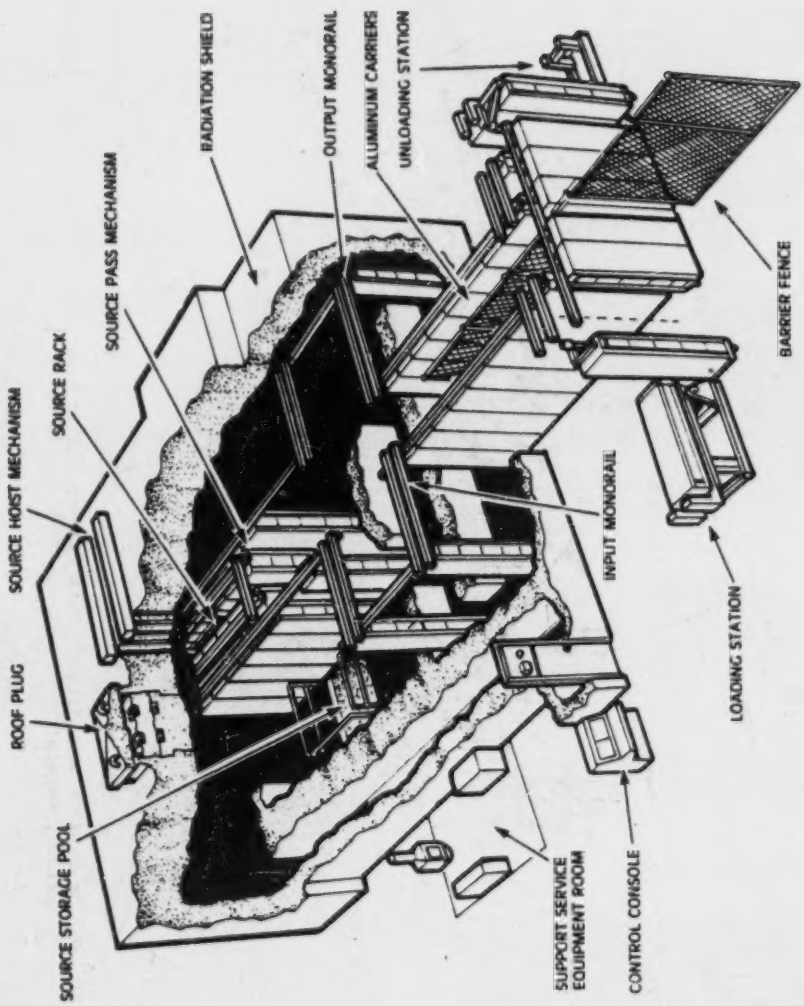

Figure V-2. Drawing of an Automatic Carrier Irradiator (Courtesy of Atomic Energy of Canada, Ltd., Ottawa, Canada).

parameters constant and increasing the net utilization efficiency would mean less cobalt-60 is needed. Cobalt-60 decays with a half life of 5.3 years, so it must be periodically replenished to maintain product throughput. On an annual basis, about 12.5 percent of the source is lost (Bradburne, 1972, p. 301).

Shielding and Auxiliary Systems

Shielding is needed to protect workers operating the facility and the general public from exposure to radiation. In gamma facilities, this biological shielding usually takes the form of five to six feet thick cement walls forming the irradiation chamber; a deep pool of water into which the rack holding the radioisotopes can be lowered to allow people to enter the chamber for repairs, maintenance, and source replenishment; and a labyrinth arrangement leading into and out of the chamber to deflect and absorb the rays.5/ Auxiliary systems are needed to deionize the water in the pool and remove excess heat, and an air handling system is needed to vent out the ozone produced. Biological shielding and venting is also required for machine sources of radiation, but no storage pool or vault is required because the machine is turned off for servicing or repair.

Machinery and Conveyors

Another important component in a cobalt-60 irradiator is the machinery to raise the source into position and move the food past the source. This machinery basically consists of a rack to hold the cobalt-60, a mechanism to move it into position, a conveyor system, a control system to regulate conveyor speed (and thus, exposure time), and the automatic safety features. The design of the conveyor system has a direct effect on the net utilization efficiency of the source. Many systems have been tried in the past and exist today (Bradburne, 1972; Chu, 1976; Cuda, 1984; Welt, 1983).

Other Capital and Operating Costs

Building space is required for offices, the control panel area, a laboratory to conduct tests to verify the dose received, a room for power sources to run the machinery, and product loading and unloading areas. Land would be needed on which to construct the facility. For a free standing irradiator to which products from various areas must be shipped, sufficient acreage is needed for trucks to turn around, for building setback requirements, etc. A free standing facility that is not part of a packing house or slaughtering plant would need to have storage space (most likely refrigerated) to hold product before or after irradiation, unless trucking schedules could be coordinated with the irradiation timetable.

Non-capital expenses include design and engineering costs, salaried and hourly labor, maintenance, supplies, utilities (water, electricity, telephone), and general business expenses like insurance and taxes. All of these items vary with the design of the irradiator and local conditions. Design and engineering can vary greatly depending on whether the facility owner decides to use an existing design or has a unique application requiring a radical

5/ Dry storage of radioisotopes is also possible and used in a few irradiators in the United Kingdom.

redesign. Salaried employees would generally consist of a plant manager, a radiation safety officer/quality control person, a maintenance person, and clerical help. Each shift would require a supervisor/plant operator and enough material handlers to load and unload the conveyor system.

Applications and Throughputs

Five foods--papayas, pork, fish, strawberries and chicken--were analyzed. The selected radiation dose levels were below the 1,000 krad (10kGy) level incorporated in the Codex Alimentarius Commission's proposed international standard for irradiated foods (Codex, 1984, p. 1). Applications were chosen to illustrate radiation's diverse uses on both animal and plant foods. According to the scientific literature, the doses absorbed would not cause noticeable off-flavors or other negative quality changes to the exposed foods. Current pre and post handling and storage procedures are considered sufficient, except irradiated fish fillets must be kept at temperatures less than 37°F or 3°C to avoid contamination with botulism toxin (see discussion in chapter II).

Costs were calculated for the following applications and corresponding doses:

° Disinfesting Hawaiian papayas to satisfy quarantine requirements for shipment to the continental United States (26 krads or 0.26 kGy).

° Inactivating trichinella spiralis, the parasite responsible for the disease trichinosis, in pork (30 krads or 0.3 kGy).

° Extending the shelf life of fish fillets by several days, thereby expanding the geographic market for fresh fish (175 krads or 1.75 kGy).6/

° Decreasing storage decay of strawberries and extending shelf life by several days (200 krads or 2 kGy).

° Reducing the numbers of common food poisoning microorganisms, such as Salmonella and Campylobacter, in fresh young chicken (250 krads or 2.5 kGy).

Throughput capacities were based on actual production conditions in appropriate geographic locations in the United States, such as a major fishing port or the California region with the greatest concentration of strawberry production. These maximum throughputs were then successively halved to approximate annual volumes of existing agricultural plants. Table V-1 lists the plant sizes analyzed for each commodity. Yearly throughputs for the pork and chicken irradiators reflect processing capacities of large and medium sized U.S. slaughtering plants.

6/ Some scientists recommend a lower dose for fish of 100 krads (1 kGy) to lessen the chance of a possible botulism hazard (Ronsivalli, et. al., 1978, p. 11). Shelf life extension would be shortened with the 100 krad dose.

Irradiators treating papayas, fish, and strawberries were assumed to be free standing facilities which would treat products from individual packing houses. Pork and chicken irradiators were assumed to be physically integrated into existing slaughtering plants. This arrangement eliminates the cold storage space, certain offices, and truck loading/unloading areas needed for a free standing facility. An integrated arrangement also allows certain personnel already employed by the slaughtering plant to handle some of the duties associated with the irradiator.

The irradiation schedules used in this analysis were designed to cause minimal disruption of existing processing and marketing schedules. Although each model irradiator was operated 24 hours a day, fish fillets, papayas, young chicken, and pork were irradiated five days per week rather than a possible seven days to coincide with the shipping and processing schedules currently used in those industries. For the integrated chicken and pork irradiators, the shorter irradiation week means that no additional cold storage capacity is required to hold carcasses for weekend irradiation. Strawberries were irradiated seven days per week, but only four months of the year. Treatment of seasonal agricultural products is more likely to follow this schedule.

Methodology and Major Assumptions

Irradiator design and operation are very specific to the particular commodity, its reaction and tolerance to radiation, national occupational safety requirements, and many other variables. However, development of cost relationships by plant size requires specific assumptions about input prices and operating procedures to provide the standardization needed to make inter-plant cost comparisons.

Capital and operating costs were estimated for the model irradiators based on information from builders and operators of commercial irradiation facilities. Reliance on their judgement and experience was essential because of the lack of single purpose food irradiators from which to collect empirical data. The costs presented here are meant to provide the reader with an idea of the magnitude of irradiation treatment costs and how these generalized costs might vary with plant size.

The major assumptions underlying the estimated unit costs are identified below.

1) Irradiators do not operate continuously. Downtime must be allowed for maintenance and source loading. In this analysis, irradiators were assumed to be processing food products for 21 hours of a 24-hour processing day. Annual volumes are based on 250 processing days per year, except for strawberries with 124 processing days per year.

2) Net utilization efficiency of the cobalt-60 was assumed to be 25 percent for all irradiators. Under actual conditions, this efficiency depends on the design of the irradiator which must consider the product's density and dose uniformity needs. Generally a trade-off exists between simpler, less expensive conveyor systems with lower cobalt-60 efficiency and more elaborate conveyor systems with higher efficiency. Net utilization efficiencies reported

in the literature range from approximately 9.5 to 35 percent (Umeda, 1983, p. 24; Jarrett, 1983, p. 154).

3) Several major cost components--biological shielding, irradiator machinery, and labor and machinery for product handling--were estimated at common throughput levels across commodities (see Appendix A). These general costs were assigned to irradiators of similar size. Land requirements were assumed to be three acres for all sizes of free standing irradiators. Costs for cobalt-60 loadings and refrigerated storage are estimated for each throughput.7/

4) For ease of computation, yearly replenishment of the decayed portion of cobalt-60 is assumed and treated as a yearly expense. Operators of irradiators with small loadings are more likely to purchase enough cobalt-60 to allow several years of maximum operation rather than incur the high transportation charges of annual replenishment. Therefore, costs may be slightly overstated for small papaya and fish irradiators.

5) Palletized boxes of product were assumed to be restacked in an arrangement compatible with the irradiator design. Overdose ratios associated with handling pallet loads of products are larger than those experienced when handling smaller loads (Dietz, 1983, p. 13). For applications where the minimum to maximum dosage ratio is large and overdosing is not a problem, foods may be able to be handled in pallet loads. To be on the conservative side, however, the authors assumed that pallets would be broken down into smaller units for radiation processing. Because of relatively high labor costs in the United States, depalletizing and repalletizing machines that reduce human labor were used for the three largest model irradiators (see Appendix V-C). Product handling is an important cost component in radiation processing. The combination of machine and laborers affects both the fixed capital costs and variable labor costs. The appropriate combination depends on the relative efficiencies and costs of these two substitutes. The combination chosen for each of the five irradiators results in minimum handling costs at capacity levels.

In addition to labor rates, land and construction costs vary regionally within the United States and around the world. If the relative prices of production inputs differ dramatically from those used here, an irradiator operator is likely to select a different combination of inputs to achieve least cost output. This would affect the scale economies. Wage rates, cost of cobalt-60 per curie, and the values assumed for other production inputs are presented in Appendix V-A.

Annualizing Fixed and Variable Costs

The costs of building and operating an irradiator are divided into fixed and variable costs. Together they constitute the total cost of operation for a given level of output. Fixed costs remain unchanged as output is altered. For example, once the biological shielding and machinery are built to accommodate a particular level of throughput, the cost of using these inputs will not change if output is reduced. In contrast, the cost of inputs such as

7/ The author assumed that four days worth of refrigerated storage was needed to hold product in case of unscheduled downtime.

utilities and hourly labor do vary with the use of the irradiator and the corresponding output. Hourly labor, supplies, utilities, and maintenance that depends on how much the facility is used are considered variable cost items.

Fixed and variable costs were expressed on an annual basis so that total costs could be divided by annual output to derive unit costs. Recurring expenses like utilities, salaries, and cobalt-60 replenishment were already expressed on a yearly basis. A capital recovery factor was used to estimate the levelized annual cost of the biological shielding, buildings, machinery, and the initial cobalt-60. This factor computes the amount needed to recover the original investment (purchase price), plus the opportunity cost of the money spent to buy the asset, over its useful life. The formula used to compute the annual costs for the capital assets is as follows:

$$\text{Levelized Annual Cost} = K \times \frac{i(1+i)^n}{(1+i)^n - 1}$$

where: K = original investment
i = interest rate
n = number of years of useful life

This approach does not take into account the effects of tax code provisions (i.e. depreciation schedules, investment tax credits, deductability of interest payments on loans, etc.). Tax considerations vary between firms and confuse the issue of what is the economic cost of the asset to the purchaser. Crucial variables in the capital recovery formula are the interest rate, or opportunity cost of money, and the assumed useful life of the asset. In this analysis, the interest rate used was 11.75 percent, the prime rate in the United States in December 1984. The useful lives for the capital assets were assumed to be 25 years for buildings and biological shielding, 10 years for machinery, and 15 years for the initial cobalt-60 loading.[8/]

Tables V-2 through V-6 contain the estimated capital and operating costs for four different sized irradiators, operated at design capacity, treating each of the five foods. These costs are expressed on an annual basis so that average unit costs can be determined. The annualized fixed and variable costs are summarized in Table V-1. Table V-1 also lists the investment requirements for each irradiator. The wide range of $1 million to $11 million reflects both the diverse volumes of product being treated and the different radiation doses being applied.

Resulting Economies of Scale

Economies of scale are reflected in the shape of a plant's long-run average cost curve. The steeper the curve, the greater the economies of scale. The long-run cost curve shows the minimum average cost of producing each output level when all inputs are variable and a firm is free to choose any plant size. One method that economists use to approximate the long-run

8/ One cost that was not explicitly considered was the cost of disposing of the low activity cobalt-60 whose usefulness is exhausted. A supplier of a radioisotope may have an arrangement to take back low-level source material. This disposal service may carry an additional charge or be included in the original price for the radioisotope.

Table V-1. Summary of Investment and Annual Costs for Selected Cobalt-60 Irradiators 1/

Commodity and Annual Throughput in Millions of Pounds	Initial Investment 2/	Annualized Fixed Costs 3/	Annual Variable Costs 4/	Annual Total Cost
	$1,000,000	$1,000	$1,000	$1,000
Fish Fillets 5/				
6	1.0	309	203	512
12	1.1	336	208	544
24	1.4	401	224	625
48	1.9	515	248	763
Papayas 5/				
12	1.0	301	204	505
24	1.2	329	216	545
48	1.5	389	302	691
96	2.4	547	428	975
Strawberries 5/				
25	2.0	514	162	676
50	3.4	835	222	1,057
100	5.8	1,388	296	1,684
200	10.5	2,518	489	3,007
Young Chicken 6/				
52	2.0	510	305	815
104	3.3	847	421	1,268
208	6.0	1,527	601	2,128
416	11.2	2,839	1,006	3,845
Pork 6/				
66.5	.9	237	197	434
133	1.1	290	207	497
266	1.6	398	285	683
532	2.5	619	328	947

1/ Costs in this table are expressed in U.S. dollars and based on a specific set of assumptions and input prices listed in Appendix V-A.

2/ Investment items include: cobalt-60, biological shielding and other building space, irradiator machinery and auxilary systems, product handling equipment, refrigerated warehouse space, design and engineering, land, and working capital.

3/ Includes the annualized costs for investment items and annual costs for cobalt-60 replenishment, fixed maintenance, insurance and taxes, and salaried personnel.

4/ Includes wages of shift supervisors/plant operators and product handlers, supplies, utilities, and variable maintenance.

5/ Free standing facility; see text for dose level. The strawberry irradiators operate 7 days a week for 4 months per year, instead of 5 days year round as do the other irradiators (see footnote 2 of table V-7).

6/ Integrated facility; see text for dose level. Split pork carcasses are assumed to move through the irradiator suspended from a monorail track. Therefore, machinery and product handling costs are different than for the other foods.

Table V-2. Capital Investment and Fixed and Variable Costs for Four Sizes of Fish Irradiators 1/

	1,190 lbs/hr. 45 ft^3/hr. 6,000,000 lbs/yr.	2,381 lbs/hr. 90 ft^3/hr. 12,000,000 lbs/yr.	4,762 lbs/hr. 181 ft^3/hr. 24,000,000 lbs/yr.	9,524 lbs/hr. 362 ft^3/hr. 48,000,000 lbs/yr.
INVESTMENT ITEMS		dollars		
Initial loading				
curies	79,600	159,400	318,700	637,500
delivery & rigging	6,000	7,000	14,000	27,000
total (rounded)	86,000	166,000	333,000	665,000
Biological shielding	285,000	285,000	300,000	300,000
Irradiator machinery	230,000	230,000	250,000	250,000
Auxilary systems	20,000	20,000	30,000	50,000
Control room and dosimetry lab	17,000	17,000	17,000	17,000
Fork lifts, palletizers	30,000	30,000	30,000	30,000
Refrigerated warehouse	20,000	40,000	80,000	160,000
Additional rooms	59,000	59,000	59,000	59,000
Design and engineering	75,000	85,000	110,000	153,000
Land	120,000	120,000	120,000	120,000
Working capital	81,000	82,000	86,000	91,000
TOTAL INITIAL INVESTMENT	1,023,000	1,134,000	1,415,000	1,895,000

(con't.)

Table V-2. Capital Investment and Fixed and Variable Costs for Four Sizes of Fish Irradiators (con't.)

	1,190 lbs/hr. 45 ft^3/hr. 6,000,000 lbs/yr.		2,381 lbs/hr. 90 ft^3/hr. 12,000,000 lbs/yr.		4,762 lbs/hr. 181 ft^3/hr. 24,000,000 lbs/yr.		9,524 lbs/hr. 362 ft^3/hr. 48,000,000 lbs/yr.	
ANNUALIZED FIXED COSTS				dollars				
Source								
initial loading		12,459		24,048		48,241		96,338
replenishment		15,000		24,000		41,000		77,000
Building and shielding		57,134		60,893		70,916		86,327
Machinery		49,050		49,050		54,305		57,808
Land		14,100		14,100		14,100		14,100
Working capital		9,518		9,635		10,105		10,693
Fixed maintenance		4,000		4,000		6,000		8,000
Insurance and taxes		19,000		21,000		27,000		36,000
Salaried employees		129,000		129,000		129,000		129,000
TOTAL (rounded)		309,000		336,000		401,000		515,000
VARIABLE COSTS								
Labor								
shift supervisors/ plant operators		101,000		101,000		101,000		101,000
product handlers 2/	(3.3)	64,000	(3.3)	64,000	(3.4)	66,000	(3.4)	66,000
Supplies		15,000		17,000		22,000		31,000
Utilities		16,000		18,000		24,000		35,000
Variable maintenance		7,000		8,000		11,000		15,000
TOTAL VARIABLE COSTS		203,000		208,000		224,000		248,000
UNIT COST $/lb.		0.0853		0.0453		0.026		0.0159

1/ Free standing facility; year round operation, 24 hours per day, 5 days per week; 175 krad (1.75 kGy) dose. The estimated costs in this table are based on a specific set of assumptions listed in Appendix V-A. Most costs are rounded to the nearest thousand dollars.

2/ The numbers in parentheses are the number of product handlers needed for each shift.

Table V-3. Capital Investment and Fixed and Variable Costs for Four Sizes of Papaya Irradiators 1/

	2,381 lbs/hr. 154 ft^3/hr. 12,000,000 lbs/yr.	4,762 lbs/hr. 309 ft^3/hr. 24,000,000 lbs/yr.	9,524 lbs/hr. 619 ft^3/hr. 48,000,000 lbs/yr.	19,048 lbs/hr. 1,238 ft^3/hr. 96,000,000 lbs/yr.
INVESTMENT ITEMS		dollars		
Initial loading				
curies	23,700	47,300	94,700	189,400
delivery & rigging	6,000	6,000	6,000	7,000
total (rounded)	30,000	53,000	101,000	196,000
Biological shielding	285,000	300,000	325,000	350,000
Irradiator machinery	230,000	250,000	325,000	500,000
Auxilary systems	20,000	30,000	30,000	30,000
Control room and dosimetry lab	17,000	17,000	17,000	17,000
Fork lifts, palletizers	30,000	30,000	30,000	198,000
Refrigerated warehouse	70,000	140,000	281,000	562,000
Additional rooms	59,000	59,000	59,000	76,000
Design and engineering	74,000	88,000	117,000	193,000
Land	120,000	120,000	120,000	120,000
Working capital	82,000	84,000	105,000	135,000
TOTAL INITIAL INVESTMENT	1,017,000	1,171,000	1,510,000	2,377,000

(con't.)

Table V-3. Capital Investment and Fixed and Variable Costs for Four Sizes of Papaya Irradiators (con't.)

	2,381 lbs/hr. 154 ft^3/hr. 12,000,000 lbs/yr.		4,762 lbs/hr. 309 ft^3/hr. 24,000,000 lbs/yr.		9,524 lbs/hr. 619 ft^3/hr. 48,000,000 lbs/yr.		19,048 lbs/hr. 1,238 ft^3/hr. 96,000,000 lbs/yr.	
ANNUALIZED FIXED COSTS				dollars				
Source								
initial loading		4,346		7,678		14,632		28,394
replenishment		9,000		11,000		17,000		27,000
Building and shielding		63,273		75,677		100,110		150,102
Machinery		49,050		54,305		67,443		127,529
Land		14,100		14,100		14,100		14,100
Working capital		9,635		9,870		12,338		15,863
Fixed maintenance		4,000		5,000		6,000		10,000
Insurance and taxes		19,000		22,000		28,000		45,000
Salaried employees		129,000		129,000		129,000		129,000
TOTAL (rounded)		301,000		329,000		389,000		547,000
VARIABLE COSTS								
Labor								
shift supervisors/ plant operators		101,000		101,000		101,000		101,000
product handlers 2/	(3.3)	64,000	(3.4)	66,000	(7)	137,000	(11)	215,000
Supplies		15,000		18,000		23,000		39,000
Utilities		17,000		22,000		30,000		54,000
Variable maintenance		7,000		9,000		11,000		19,000
TOTAL VARIABLE COSTS		204,000		216,000		302,000		428,000
UNIT COST $/lb.		0.0421		0.0227		0.0144		0.0102

1/ Free standing facility; year round operation, 24 hours per day, 5 days per week; 26 krad (0.26 kGy) dose. The estimated costs in this table are based on a specific set of assumptions listed in Appendix V-A. Most costs are rounded to the nearest thousand dollars.

2/ The numbers in parentheses are the number of product handlers needed for each shift.

Table V-4. Capital Investment and Fixed and Variable Costs for Four Sizes of Strawberry Irradiators 1/

	9,600 lbs/hr. 448 ft^3/hr. 25,000,000 lbs/yr.	19,200 lbs/hr. 896 ft^3/hr. 50,000,000 lbs/yr.	38,400 lbs/hr. 1,792 ft^3/hr. 100,000,000 lbs/yr.	76,800 lbs/hr. 3,584 ft^3/hr. 200,000,000 lbs/yr.
INVESTMENT ITEMS		dollars		
Initial loading				
curies	652,800	1,305,600	2,611,200	5,222,400
delivery & rigging	27,000	49,000	97,000	188,000
total (rounded)	680,000	1,355,000	2,708,000	5,410,000
Biological shielding	325,000	350,000	450,000 2/	650,000
Irradiator machinery	325,000	500,000	638,000 2/	1,050,000
Auxilary systems	50,000	50,000	53,000 2/	55,000
Control room and dosimetry lab	17,000	17,000	17,000	17,000
Fork lifts, palletizers	30,000	198,000	258,000 2/	353,000
Refrigerated warehouse	204,000	406,000	814,000	1,624,000
Additional rooms	59,000	76,000	101,000	160,000
Design and engineering	169,000	295,000	504,000	932,000
Land	120,000	120,000	120,000	120,000
Working capital	62,000	75,000	92,000	137,000
TOTAL INITIAL INVESTMENT	2,041,000	3,442,000	5,755,000	10,508,000

(con't.)

Table V-4. Capital Investment and Fixed and Variable Costs for Four Sizes of Strawberry Irradiators (con't)

	9,600 lbs/hr. 448 ft^3/hr. 25,000,000 lbs/yr.	19,200 lbs/hr. 896 ft^3/hr. 50,000,000 lbs/yr.	38,400 lbs/hr. 1,792 ft^3/hr. 100,000,000 lbs/yr.	76,800 lbs/hr. 3,584 ft^3/hr. 200,000,000 lbs/yr.
ANNUALIZED FIXED COSTS		dollars		
Source				
initial loading	98,511	196,298	392,306	783,743
replenishment	88,000	170,000	340,000	680,000
Building and shielding	96,977	143,336	236,304	423,868
Machinery	70,948	131,032	166,243	255,408
Land	14,100	14,100	14,100	14,100
Working capital	7,285	8,813	10,810	16,098
Fixed maintenance	9,000	15,000	26,000	49,000
Insurance and taxes	40,000	67,000	113,000	207,000
Salaried employees 3/	89,000	89,000	89,000	89,000
TOTAL (rounded)	514,000	835,000	1,388,000	2,518,000
VARIABLE COSTS				
Labor 3/				
shift supervisors/ plant operators	70,000	70,000	70,000	70,000
product handlers 4/	(7) 63,000	(11) 99,000	(15) 135,000 2/	(28) 251,000
Supplies	11,000	20,000	34,000	62,000
Utilities	13,000	23,000	41,000	76,000
Variable maintenance	5,000	10,000	16,000	30,000
TOTAL VARIABLE COSTS	162,000	222,000	296,000	489,000
UNIT COST $/lb.	0.027	0.0211	0.0168	0.015

1/ Free standing facility; 4 months per year operation, 24 hours per day, 7 days per week; 200 krad (2.0 kGy) dose. The estimated costs in this table are based on a specific set of assumptions listed in Appendix V-A. Most costs are rounded to the nearest thousand dollars.

2/ Average of costs for 1,000 ft^3/hr. and 2,500 ft^3/hr.

3/ Employees other than plant manager are hired for 4 months of the year. Radiation safety officer, shift supervisors, and plant operators receive 30% higher wages to compensate for part time employment. Plant manager is hired for the full year to maintain the irradiator.

4/ The numbers in parentheses are the number of product handlers needed for each shift.

Table V-5. Capital Investment and Fixed and Variable Costs for Four Sizes of Chicken Irradiators 1/

	9,905 lbs/hr. 430 ft^3/hr. 52,000,000 lbs/yr.	19,810 lbs/hr. 859 ft^3/hr. 104,000,000 lbs/yr.	39,619 lbs/hr. 1,717 ft^3/hr. 208,000,000 lbs/yr.	79,238 lbs/hr. 3,434 ft^3/hr. 416,000,000 lbs/yr.
INVESTMENT ITEMS		dollars		
Initial loading				
curies	947,000	1,894,300	3,788,500	7,577,100
delivery & rigging	35,000	69,000	133,000	266,000
total (rounded)	982,000	1,963,000	3,922,000	7,843,000
Biological shielding	325,000	350,000	450,000 2/	650,000
Irradiator machinery	325,000	500,000	638,000 2/	1,050,000
Auxilary systems	50,000	50,000	53,000 2/	55,000
Control room and dosimetry lab	17,000	17,000	17,000	17,000
Fork lifts, palletizers	30,000	30,000	258,000 2/	353,000
Refrigerated warehouse	0	- 0	0	0
Additional rooms	0	0	0	0
Design and engineering	173,000	291,000	534,000	997,000
Land	0	0	0	0
Working capital	88,000	114,000	153,000	243,000
TOTAL INITIAL INVESTMENT	1,990,000	3,315,000	6,025,000	11,208,000

(con't.)

Table V-5. Capital Investment and Fixed and Variable Costs for Four Sizes of Chicken Irradiators (con't.)

	9,905 lbs/hr. 430 ft^3/hr. 52,000,000 lbs/yr.	19,810 lbs/hr. 859 ft^3/hr. 104,000,000 lbs/yr.	39,619 lbs/hr. 1,717 ft^3/hr. 208,000,000 lbs/yr.	79,238 lbs/hr. 3,434 ft^3/hr. 416,000,000 lbs/yr.
ANNUALIZED FIXED COSTS		dollars		
Source				
initial loading	142,262	284,378	568,177	1,136,210
replenishment	112,000	223,000	441,000	876,000
Building and shielding	64,526	82,443	125,419	208,489
Machinery	70,947	101,603	166,243	255,408
Land	0	0	0	0
Working capital	10,340	13,395	17,978	28,553
Fixed maintenance	9,000	15,000	28,000	52,000
Insurance and taxes	38,000	64,000	117,000	219,000
Salaried employees	63,000	63,000	63,000	63,000
TOTAL (rounded)	510,000	847,000	1,527,000	2,839,000
VARIABLE COSTS				
Labor				
shift supervisors/ plant operators	101,000	101,000	101,000	101,000
product handlers 3/	(6) 117,000	(9) 176,000	(12) 234,000 2/	(21) 410,000
Supplies	35,000	58,000	107,000	199,000
Utilities	35,000	58,000	107,000	199,000
Variable maintenance	17,000	28,000	52,000	97,000
TOTAL VARIABLE COSTS	305,000	421,000	601,000	1,006,000
UNIT COST $/lb.	0.0157	0.0122	0.0102	0.0092

1/ Integrated facility; year round operation, 24 hours per day, 5 days per week; 250 krad (2.5 kGy) dose. The estimated costs in this table are based on a specific set of assumptions listed in Appendix V-A. Most costs are rounded to the nearest thousand dollars.

2/ Average of costs for 1,000 ft^3/hr. and 2,500 ft^3/hr.

3/ The numbers in parentheses are the number of product handlers needed for each shift.

Table V-6. Capital Investment and Fixed and Variable Costs for Four Sizes of Pork Irradiators 1/

	12,190 lbs/hr. 366 ft^3/hr. 66,560,000 lbs/yr.	24,381 lbs/hr. 731 ft^3/hr. 133,120,000 lbs/yr.	48,762 lbs/hr. 1,463 ft^3/hr. 266,240,000 lbs/yr.	97,524 lbs/hr. 2,926 ft^3/hr. 532,480,000 lbs/yr.
INVESTMENT ITEMS		dollars		
Initial loading				
curies	139,900	279,800	559,500	1,119,100
delivery & rigging	7,000	13,000	21,000	42,000
total (rounded)	147,000	293,000	581,000	1,161,000
Biological shielding	300,000	325,000	350,000	550,000
Irradiator machinery 2/	275,000	305,000	365,000	435,000
Auxilary systems	30,000	30,000	50,000	55,000
Control room and dosimetry lab	17,000	17,000	17,000	17,000
Fork lifts, palletizers 2/	0	0	0	0
Refrigerated warehouse	0	0	0	0
Additional rooms	0	0	0	0
Design and engineering	77,000	97,000	136,000	222,000
Land	0	0	0	0
Working capital	63,000	65,000	84,000	92,000
TOTAL INITIAL INVESTMENT	909,000	1,132,000	1,583,000	2,532,000

(con't.)

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Table V-6. Capital Investment and Fixed and Variable Costs for Four Sizes of Pork Irradiators (con't)

	12,190 lbs/hr. 366 ft^3/hr. 66,560,000 lbs/yr.	24,381 lbs/hr. 731 ft^3/hr. 133,120,000 lbs/yr.	48,762 lbs/hr. 1,463 ft^3/hr. 266,240,000 lbs/yr.	97,524 lbs/hr. 2,926 ft^3/hr. 532,480,000 lbs/yr.
ANNUALIZED FIXED COSTS		dollars		
Source				
initial loading	21,296	42,447	84,169	168,193
replenishment	22,000	37,000	68,000	131,000
Building and shielding	49,366	55,004	63,023	98,857
Machinery	53,429	58,684	72,698	85,837
Land	0	0	0	0
Working capital	7,403	7,638	9,870	10,810
Fixed maintenance	4,000	5,000	7,000	12,000
Insurance and taxes	17,000	21,000	30,000	49,000
Salaried employees	63,000	63,000	63,000	63,000
TOTAL (rounded)	237,000	290,000	398,000	619,000
VARIABLE COSTS				
Labor				
shift supervisors/ plant operators	101,000	101,000	101,000	101,000
product handlers 3/	(3) 59,000	(3) 59,000	(6) 117,000	(6) 117,000
Supplies	15,000	19,000	27,000	44,000
Utilities	15,000	19,000	27,000	44,000
Variable maintenance	7,000	9,000	13,000	22,000
TOTAL VARIABLE COSTS	197,000	207,000	285,000	328,000
UNIT COST $/lb.	0.0065	0.0037	0.0026	0.0018

1/ Integrated facility; year round operation, 24 hours per day, 5 days per week; 30 krad (0.30 kGy) dose. The estimated costs in this table are based on a specific set of assumptions listed in Appendix V-A. Most costs are rounded to the nearest thousand dollars.
2/ Split pork carcasses are assumed to move through the irradiator suspended from a monorail track.
3/ The numbers in parentheses are the number of product handlers needed for each shift.

cost curve is to examine a series of short-run cost curves for individual plant sizes and select minimum unit costs for each output level.

Short-run cost curves for each size irradiator were estimated by computing costs at 25, 50, 75, and 100 percent of capacity. Capacity is defined as the maximum throughput level for which the plant was designed. Variable costs were estimated for each level of capacity utilization. Fixed costs are independent of what portion of capacity is used and remain constant as throughput drops.

Table V-7 lists irradiation treatment costs per pound based on the specific set of assumptions and input prices used in this analysis. Also included in table V-7 are farm and wholesale prices for comparison with irradiation costs. Costs are for in-house irradiators operated at design capacity. Unit costs for the applications and volumes analyzed range from 8.5 to 0.2 cents per pound. All five irradiation applications exhibit economies of scale, as demonstrated by their decreasing unit costs as size is doubled. This means that, considering only the treatment cost, larger irradiators would be able to treat products at a lower unit cost than small irradiators. However, in all cases the scale economies become less pronounced as size increases. Potential scale economies become less important at annual volumes greater than 50 million pounds. For example, the unit costs for the two largest strawberry irradiators operating at full capacity differed by only 0.2 cents per pound.

Source of Scale Economies

Economies of scale result from production inputs expanding less than proportionally with volume. To determine the source of the economies, one examines how the major components change with size. Cobalt-60, building and shielding, machinery, and labor accounted for 80 to 85 percent of unit costs in these scenarios. For a cobalt-60 irradiator, the most important sources of production economies are labor, buildings and shielding, and machinery.

Certain employees--plant manager, quality control person, maintenance and clerical personnel, and shift supervisors--are needed regardless of the size of the irradiator. Spreading their fixed salaries over large outputs, lowers average fixed labor costs.9/ When salaried employees are a major cost item, such as in the fish irradiators which span a smaller size range, favorable economies of scale are captured with relatively small increases in size. Conversely, the number of material handlers needed does vary with irradiator size, so as their numbers grow and they become a more important component of labor costs, scale economies attributed to labor costs are moderated. This moderates overall scale economies and lessens the decline in unit costs for irradiators in the large volume range. Unit costs in table V-7 drop by 4 and 2 cents per pound between the two smallest fish and papaya irradiators, respectively, compared with a 0.1-cent drop between the largest two chicken irradiators.

9/ Salaries were not assumed to change as irradiator size increased because of the relatively small work force (all sizes employed less than 40 people) and the fact that the skill levels of the employees do not change much as size increases.

Table V-7. Irradiation Unit Costs

Commodity and Annual Throughput	Dose	Irradiation Unit Costs 1/	Farm or Wholesale Price 2/
millions of pounds	krad (kGy)	cents per pound	
Fish fillets	175 (1.75)		
6		8.5	
12		4.5	150 - 155
24		2.6	
48		1.6	
Papayas	26 (0.26)		
12		4.2	
24		2.3	18.9
48		1.4	
96		1.0	
Strawberries[3]	200 (2.0)		
25		2.7	
50		2.1	53.2
100		1.7	
200		1.5	
Young Chicken	250 (2.5)		
52		1.6	
104		1.2	55.5
208		1.0	
416		0.9	
Pork	30 (0.3)		
66.5		0.7	
133		0.4	109
266		0.3	
532		0.2	

1/ Unit costs are based on a specific set of assumptions and input prices listed in Appendix V-A.
2/ Papaya and strawberry prices are farm values for 1983; pork price is wholesale price for 1983; and fish and chicken prices are wholesale prices for 1984.
3/ For strawberry irradiators, employees other than the plant manager, are hired for 4 months of the year. Radiation safety officer, shift supervisors, and plant operators receive 30 percent bonus to compensate for part time employment. Plant manager is hired for the full year to maintain the irradiator during the non-use season.

Buildings, shielding, and machinery costs are likely to follow the general construction relationship where productive capacity increases faster than cost, although at a declining rate as scale increases (McGee, 1974, p. 58). This relationship also contributes to the existence of larger scale economies for small volume irradiators. In addition, larger plants can make use of labor-saving machinery not justified at lower volumes. Workers in the three smallest irradiators restacked pallets by hand, whereas the largest irradiators used depalletizing and repalletizing machines for this task.

Cobalt-60 is an important cost item, especially for large capacity irradiators. However, cobalt-60 is not a source of production economies because cobalt needs are directly related to hourly throughput. Only minor economies could be realized through cobalt-60 suppliers offering volume discounts. As plant capacity increases for each dose level in table V-7, cobalt becomes a larger portion of total costs and fewer scale economies are possible. This is illustrated by the declining rate of reduction in unit costs for all applications.

Raising the dose of radiation applied to the food also causes cobalt-60 to become a greater portion of total costs. Therefore, large capacity irradiators applying higher doses would demonstrate less scale economies. The declining rate of reduction in unit costs for the chicken and strawberry irradiators as throughput increases illustrates this.

Treatment of Seasonal Products

Irradiators are likely to operate at less than design capacity during part of the year if irradiation is used to treat seasonal products such as fruits and vegetables. Even commodities grown year round like papaya have definite seasonal harvest patterns. To accomodate the seasonal peaks requiring large hourly capacity, irradiators would have excess capacity during off periods.

Another contributor to unused capacity would be an unexpected drop in sales. This could occur for many reasons including a change in consumers' incomes and food expenditures, lower prices of substitute foods, negative publicity about a commodity's qualities, or a consumer boycott of radiation-treated foods similar to the Japanese boycott of irradiated potatoes (see chapter III).

Operating an irradiator at less than design capacity raises unit costs because of the fixed nature of most irradiator costs. A large irradiator treating small volumes of products has less output over which to spread its high fixed costs. The short-run cost curves for strawberry irradiators, shown in figure 3, illustrate the point clearly. These short-run cost curves were estimated by computing costs at 25, 50, 75, and 100 percent of design capacity. If 50 million pounds of strawberries were treated in a facility designed for that annual volume, the unit cost would be close to 2 cents per pound. A plant built to handle double that volume would incur a unit cost of 3 cents per pound. If the largest strawberry irradiator only processed 50 million pounds per year, it would be running at 25 percent of capacity and unit costs would be above 5 cents per pound.

Strawberries

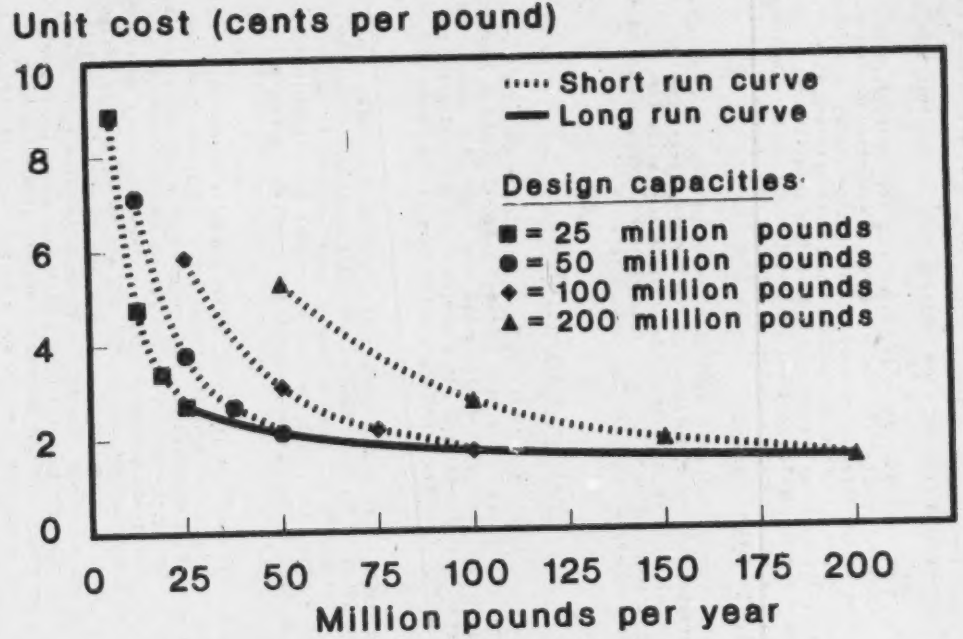

Figure 3. Irradiation unit costs for free standing facility; 4 months' operation per year, 24 hours per day, 7 days per week; 200 krad (2 kGy) dose.

Locating an irradiator in agricultural production areas with sequential harvest times for different irradiation-compatible commodities or irradiating non-agricultural items during off seasons would lessen this under utilization problem.[10/] Animal products are subject to less seasonal fluctuations, but cyclical swings over time could adversely affect use of irradiator capacity.

Sensitivity Analyses

The unit costs in table V-7 are based on a specific set of assumptions and input prices. The following sections discuss how these unit costs change when adjustments are made to the irradiation schedule, the price of cobalt-60, and whether the irradiator is free standing or part of a packing plant.

Extending the Irradiation Schedule

One of the assumptions underlying the unit costs for fish fillets, papayas, chicken, and pork is that the irradiator runs just five days per week to coincide with the filleting, packing, and slaughtering schedule. For large plants with sizable cobalt-60 investments, this schedule may be too costly. Spreading the same volume over seven days instead of five would reduce hourly throughput and the corresponding cobalt-60 loading. Variable costs, especially labor, would rise unless the lower hourly throughput levels reduced product handling costs enough to compensate for the two extra days of labor costs.

In the case of the chicken irradiators with large cobalt-60 loadings, switching to a seven-day schedule drops unit costs for the same volumes by 0.2 cent per pound, for an average of 18 percent over the sizes analyzed (table V-8). As pointed out earlier, this extended treatment schedule could disrupt processing and shipping schedules or require extra cold storage space. This would reduce potential cost savings from extending the irradiation schedule.

Table V-8. Unit Costs for Chicken Irradiators: Five Versus Seven Days Per Week Schedule [1/]

Annual Throughput in Millions of Pounds	5 Days	7 Days	Decline in Unit Cost
	cents per pound		percent
52	1.6	1.4	13
104	1.2	1.0	17
208	1.0	0.8	20
416	0.9	0.7	22

1/ Unit costs are based on a specific set of assumptions and input prices listed in Appendix V-A.

10/ Refer to discussion of multi-purpose irradiators on page V-2.

Sensitivity to Cobalt-60 Prices

Prospective users of gamma radiation are also interested in how sensitive the cost of the treatment is to the price of the radioisotope. What would the effect be if the price of cobalt-60 doubled? Raising the price of cobalt from the $1 per curie level used to estimate the unit costs listed in table V-7 to $2 per curie affects only source cost, replenishment cost, and insurance and taxes.[11/] Other components--shipping charges, design and engineering, utilities, etc.--do not change since the amount of cobalt-60 is unchanged. Unit costs under a $2 per curie price for cobalt-60 are compared with the original unit costs in table V-9.

In absolute terms, an increase in cobalt-60 prices raises unit costs by the same amount for the four sizes of irradiators for each application. This is because there is a constant relationship between throughput and curie needs for each application. For example, irradiation costs for the fish irradiators all increase by a little less than 0.4 cent per pound when the price of cobalt-60 is doubled to $2 per curie. The smallest effect is for papayas and pork because the low doses they receive make cobalt-60 a smaller portion of their costs.

The increasing percentage difference as volume doubles occurs because the absolute cost increase becomes larger in relation to the unit cost. As expected, an increase in cobalt-60 prices has the greatest effect on high volume irradiators administering higher doses where source costs are a major portion of total costs. However, even for strawberries where the increase is largest, the cost increase is less than 1 cent per pound. A higher price for cobalt-60 will also increase the initial investment.

Free Standing Versus Integrated

Another issue of interest is how unit costs differ between free standing facilities that treat products from many individual producers versus an irradiator physically integrated into a slaughtering or packing operation. An integrated irradiator would not incur the labor costs of unloading trucks and the costs of cold storage space, loading docks, and certain auxiliary rooms. These costs were subtracted from the free standing fish, papaya, and strawberry irradiators to determine the effect on unit costs of switching to an integrated arrangement. Land costs were also assumed to be zero since the irradiator would be located adjacent to the packing house on land already owned by the firm, for which the firm has no alternative use. The costs for plant manager, maintenance person, and clerical help were shared with the packing house. Table V-10 reports the unit costs for each arrangement and the percentage difference between them. Unit costs under an integrated arrangement were 15 to 27 percent lower than their free standing counterparts.

The trade-off in switching from a free standing to an integrated irradiator is that a single packing house's volume may be too low to realize any significant economies of scale. Although costs for some items would be saved, the integrated facility may not be able to treat enough throughput to realize economies of scale. For example, an irradiator integrated into a

11/ Costs for shipping the cobalt-60 and loading it into the source rack are separate cost items.

Table V-9. Sensitivity of Irradiation Unit Costs to Price of Cobalt-60 1/

Commodity and Annual Throughput	Dose	$1 per curie	$2 per curie 2/	Difference in Unit Costs
millions of lbs.	krad (kGy)	cents per pound		percent
Fish fillets				
6	175	8.53	8.90	4.3
12	(1.75)	4.53	4.89	7.9
24		2.60	2.97	14.2
48		1.59	1.96	23.3
Papayas				
12	26	4.21	4.26	1.2
24	(0.26)	2.27	2.33	2.6
48		1.44	1.49	3.5
96		1.02	1.07	4.9
Strawberries				
25	200	2.70	3.46	28.1
50	(2.0)	2.11	2.87	36.0
100		1.68	2.44	45.2
200		1.50	2.26	50.7
Young chicken				
52	250	1.57	2.07	31.8
104	(2.5)	1.22	1.72	41.0
208		1.02	1.53	50.0
416		0.92	1.43	55.4
Pork				
66.5	30	0.65	0.71	9.2
133	(0.3)	0.37	0.43	16.2
266		0.26	0.31	19.2
532		0.18	0.24	33.3

1/ Unit costs are based on a specific set of assumptions and input prices listed in Appendix V-A.
2/ This increase affects only source cost, replenishment cost, and insurance and taxes. All other components remain the same.

Table V-10. Unit Costs for Free Standing Versus Integrated Irradiators 1/

Commodity and Annual Throughput in Millions of Pounds	Free Standing	Integrated 2/	Difference between Free Standing and Integrated
	cents per pound		percent
Fish fillets:			
6	8.53	6.77	21
12	4.53	3.61	20
24	2.60	2.09	20
48	1.59	1.30	18
Papayas:			
12	4.21	3.22	24
24	2.27	1.71	25
48	1.44	1.07	26
96	1.02	0.74	27
Strawberries:			
25	2.70	2.20	19
50	2.11	1.75	17
100	1.68	1.41	16
200	1.50	1.27	15

1/ The unit costs in this table are based on a specific set of assumptions listed in Appendix V-A.
2/ The costs of the following items were assumed to be zero: loading docks, office space (apart from the control room and dosimetry lab), maintenance rooms, labor to unload trucks, building and cooling refrigerated storage space, and land. Only 15 percent of plant manager's time, 30 percent of maintenance person's time, and 50 percent clerical person's time was allocated to integrated irradiator. Salary costs reflect this allocation.

fish filleting plant with an annual volume of 48 million pounds could treat the fillets for 0.3 cent less per pound than a free standing irradiator of the same volume. However, it is more likely that a single fish filleting plant would have an annual volume closer to 6 or 12 million pounds. Unit costs for these two integrated facilities are 6.8 and 3.6 cents per pound, respectively, compared with a lower treatment cost of 1.6 cents per pound for the largest free standing fish irradiator. This 1.6-cents treatment cost, however, does not include transportation to a free standing irradiator. Adding transportation charges to the treatment cost for the largest free standing irradiator may raise complete costs to the same level as smaller integrated irradiators where no extra transportation is needed.

Comparison with Public Health Benefits

In chapter IV, Tanya Roberts developed public health costs for diseases transmitted by fresh pork and chicken. Appropriate doses of radiation could reduce the incidence of these diseases.

Irradiating chicken to kill Salmonella and Campylobacter would cost about 1.5 cents per pound, for the treatment alone, for medium and large chicken processing plants.[12/] Multiplying this cost by the 10.3 billion pounds of fresh chicken these plants produce annually equals $155 million. Medium and large hog slaughtering plants would incur costs of about 0.7 cent a pound to treat pork carcasses with the low dose needed to prevent trichinosis and toxoplasmosis. Multiplying this cost by the plants' annual output of 11.3 billion pounds results in a total annual cost of $80 million. In both cases, the medium and large chicken and hog plants account for about 80 to 85 percent of total production (tables V-11 and V-12). Average irradiation treatment costs for the remaining 15 to 20 percent of production would be substantially higher. In addition, there are label change costs, costs for regulatory oversight, and other private and public costs associated with this process.

The potential benefits summarized in table V-13 are based on the public accepting and purchasing irradiated foods. Irradiation of chicken and pork appears to have favorable benefit to cost ratios of 2 or more. Other control options may have higher net benefits than irradiation. Some of these options are discussed in chapter VII.

Table V-13. Comparison of Annual Benefits vs. Costs

	Benefits	Costs 1/	B/C	Net Benefits
	---million dollars---			million dollars
Pork 2/	186-280	80	2.3-3.5	106-200
Chicken 3/	341-653	155	2.2-4.2	186-498

1/ Costs are for medium and large plants using in-house irradiators physically integrated into the plants. Treatment costs are based on a specific set of assumption and input prices (see Appendix V-A). Examples of private and public costs not included in these estimates are listed in footnote 12 below.
2/ Assuming 86 percent of U.S. pork is irradiated at 50 krads which is sufficient to prevent human trichinosis and toxoplasmosis.
3/ Assuming 81 percent of U.S. chicken is irradiated at 250 krads which eliminates campylobacteriosis and 93 percent of salmonellosis cases.

12/ The irradiation costs discussed in this chapter do not include the expense of a possible educational campaign to acquaint consumers with irradiation, research and development monies, the public costs of training inspectors about this new technology, the disposal costs of low-level radioactive waste, and other potential costs incurred by the food firm or the Government. Also excluded are unforeseen adverse health effects of consuming irradiated foods.

Table V-11. Size Distribution of U.S. Chicken Processing Plants, FY 1984

Annual Volume of Whole and Cut Up Chicken	Number of Plants	Percent of Total U.S. Production
millions of pounds	number	percent
25.9 and less	91	3
26 to 51.9	49	16
52 to 77.9 1/	32	16
78 to 103.9	36	26
104 to 129.9	16	14
130 to 155.9	8	9
156 to 181.9	3	4
182 to 207.9	3	4
208 and over	3	8
Total	241	100

Total pounds of whole and cut up chicken packed in FY 1984 was 12.7 billion.
1/ Plants packing 52 million pounds or more of chicken per year were considered medium or large plants in this study.
Source: Food Safety and Inspection Service, USDA.

Table V-12. Size Distribution of Federally Inspected U.S. Hog Slaughtering Plants, FY 1984

Size of Plant: Number of Head Slaughtered Annually	Equivalent Annual Slaughter 1/	Number of Plants	Percent of Total U.S. Slaughter
number	millions of pounds	number	percent
Under 10,000	less than 1.6	1208	1.0
10,000 to 99,999	1.6 to 16	114	4.0
100,000 to 399,999	16 to 64	36	9.5
400,000 to 699,999 2/	64 to 112 2/	15	9.5
700,000 to 999,999	112 to 160	19	19.0
1,000,000 to 1,299,999	160 to 208	12	16.5
1,300,000 to 1,599,999	208 to 256	8	15.0
1,600,000 to 1,899,999	256 to 304	5	11.0
1,900,000 and over	304 and over	5	14.5
TOTAL	13,232	1422	100

1/ Annual slaughter equivalents were calculated by author based on assumption of one hog equaling a carcass weight of 160 pounds.
2/ Plants slaughtering 400,000 head per year (or 64 million pounds) or more were considered medium or large plants in this study.
Source: Food Safety and Inspection Service, USDA.

Conclusions and Other Considerations

Irradiation is a capital intensive technology that demonstrates economies of scale with treatment costs declining as the irradiator's size increases. For the commodities included in this analysis, plant economies of scale are pronounced for irradiators treating less than 30 million pounds per year, but become less important at annual volumes greater than 50 million pounds. Irradiators of this size or less will not be able to achieve the lower unit costs possible with higher throughputs.

Food and agriculture firms that do not have the volumes to justify an in-house irradiator may have to join with other firms and build a free standing, centrally-located irradiator to treat their combined products. Smaller firms could also use the services of a contract irradiator who would charge a fee for the irradiation treatment. These fees are expected to be higher than costs for an in-house irradiator because the flexibility needed to handle a variety of products sacrifices operational efficiency and raises costs. Also, the contract irradiator wants to achieve a profit from the service. For seasonal products, however, the contractor's fee may be less than the in-house cost because the contract facility could be more efficiently used by treating other products during the rest of the year.

For free standing and contract facilities, the cost of shipping the commodity to the irradiator is an added cost. As free standing irradiators increase in size and production density remains constant, they will have to draw from larger geographic areas for their throughput. The transportation costs of getting the commodities to the larger irradiator may outweigh any gains in plant scale economies. This may bring the total cost of using a small irradiator more closely in line with that of a large irradiator.

An analysis of production economies is only the first step in determining the economic feasibility of a process. Irradiation's competitiveness with alternative techniques--in terms of cost, acceptance by processors and consumers, and compatibility with current marketing practices--is crucial. Another consideration is whether the irradiation treatment would introduce too long of a delay between harvest and retail for highly perishable commodities, such as strawberries. Irradiation's economic feasibility would be strengthened if there is a consolidating point early in the marketing chain, so that additional transportation to the irradiator is not incurred. Finally, prospective users of radiation processing must determine whether irradiation offers benefits that are equal to, or preferably greater than, the costs.

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APPENDIX V-A.

Budget Item	Formulae and Assumptions	Source
FIXED COSTS (All costs expressed in U.S. dollars.)		
Integrated and Free Standing Facilities		
Curie load	# of curies = $\frac{85 \times \text{throughput in lbs. per hr.} \times \text{dose (in megarads)}}{\text{net utilization efficiency}}$ Net utilization efficiency was assumed to be 25% for all irradiators for this analysis. Actual net utilization efficiency depends on the design of the irradiator which must consider product density and dose uniformity needs. Net utilization efficiency is expressed as a fraction of 1, where 1 = 100% ^{60}Co utilization efficiency. An additional 12.5% for yearly decay was added to initial loading for those irradiators operating year round.	Jarrett, 1983, p. 150-51. Formula modified by author.
	Price of ^{60}Co assumed to be $1.00 per curie for this analysis.	Atomic Energy of Canada, Ltd.
Delivery of ^{60}Co (cask rental and transport)	$5000 per cask (cask holds 200,000 curies)	Industry sources.
Loading of ^{60}Co (labor and crane rental)	$1000 per 100,000 curies	Industry sources and published studies.
Source replenishment	12.5% required each year (delivery and loading costs same as above) to maintain previous year's throughput.	Deitch, et. al., 1972, p. 65.

Budget Item	Formulae and Assumptions	Source
Biological Shielding	Costs for concrete cell and labrinth and water-filled pool were estimated for six throughput levels as follows: 100 ft^3/hr — $285,000 250 ft^3/hr — $300,000 550 ft^3/hr — $325,000 1,000 ft^3/hr — $350,000 2,500 ft^3/hr — $550,000 4,000 ft^3/hr — $650,000	Industry sources and author's estimates.
Irradiator Machinery: •source hoist and plaque } A •control panel •mechanical interlocks •conveyor } B •carriers	Costs were estimated for six throughput levels as follows: 100 ft^3/hr — $150,000 (A) + $80,000 (B) 250 ft^3/hr — $150,000 + $100,000 550 ft^3/hr — $175,000 + $150,000 1,000 ft^3/hr — $200,000 + $300,000 2,500 ft^3/hr — $225,000 + $550,000 4,000 ft^3/hr — $250,000 + $800,000	Industry sources and author's estimates.
Auxilary Systems: •deionizer •chiller •air handling	Costs were estimated for six throughput levels as follows: 100 ft^3/hr — $40,000 250 ft^3/hr — $50,000 550 ft^3/hr — $50,000 1,000 ft^3/hr — $50,000 2,500 ft^3/hr — $55,000 4,000 ft^3/hr — $55,000 For irradiators with loadings less than 500,000 curies of ^{60}Co, pool chiller not needed and $20,000 subtracted from above estimates.	Industry sources, Appendix C of Bloomster, et. al., 1984, and author's estimates.

Budget Item	Formulae and Assumptions	Source
Control room and dosimetry lab	400 ft^2 at cost of $35 per ft^2. A 20% overhead construction fee is added to the calculated cost.	Author's assumption for room size and construction fee. Cost per ft^2 from Means Square Foot Costs 1984, p. 163.
Fork lifts, palletizers	Cost of forklifts and palletizers estimated for six levels of throughput (see Appendix C).	See sources listed in Appendix C.
Design and engineering of total facility layout, product movement, ^{60}Co utilization, etc. Varies widely with experience and knowledge base.	Estimated at 10% of facility cost.	Author's assumption.
Fixed maintenance	35% of total maintenance (total maintenance estimated at 1.5% of facility cost).	Industry sources.
Insurance and taxes	2% of facility and land investment.	Deitch, et. al., 1972, p. 80.
Working capital	3 months' bills for labor, supplies, and utilities. For irradiators operating only 4 months per year, working capital equals 1 month's bills.	Author's assumption.
Salaried Personnel	Annual Salaries: Plant Manager: $35,000 + $10,500 for fringes = $45,000. For integrated facility only 15% of manager's time allocated to irradiator. Radiation safety officer/quality control (RSO/QC): $30,000+ $9,000 for fringes = $39,000	30% for fringes as suggested by the Office of Wages and Industrial Relations, U.S. Bureau of Labor Statistics. Base salary for RSO/QC from discussion with health physicist in Ionizing Radiation Branch, U.S. Health and Human Services.

Budget Item	Formulae and Assumptions	Source
Salaried Personnel (cont'd)	Maintenance person: $20,000 + $6,000 for fringes = $26,000. For integrated facility only 30% of maintenance person's time allocated to irradiator. The above personnel only work one shift a day and are considered "on call" for emergencies. Clerical: $14,000 + $4,200 for fringes = $18,200. For integrated facility only 50% of clerical person's time allocated to irradiator. Clerical person only works one shift a day.	Maintenance and clerical wages estimated from information provided by the Office of Wages and Industrial Relations, BLS. Amount of time allocated in an integrated facility based on industry sources and author's assumptions.
Free Standing Facilities Only Land	3 acres for trucks to turn around, parking lot, landscaping, etc. at $40,000 an acre. (Same for all sizes of irradiators.) Actual land costs vary widely.	Acreage requirement from industry sources. Land cost from Appendix C of Bloomster et. al., 1984.
Refrigerated warehouse	Space needed was based on storing four days' worth of throughput in case of unscheduled down times or shipping foul-ups. Product is stacked 15 feet high. 25% additional space allowed for aisles and other unusable space. Cost of $54 per ft^2, a 20% overhead construction fee is added to the calculated cost.	Author's assumptions. Capacity of Refrigerated Warehouses, Statistical Reporting Service, USDA, April 1984, p. 5. Cost per ft^2 from Dodge Construction Systems Costs, 1984, p. 32.

Budget Item	Formulae and Assumptions	Source
Additional rooms and loading/unloading area	1,000 ft^2 for offices, mechanical room, bathroom, and lunchroom. (Same for all sizes of irradiators.) Loading and unloading area depends on throughput and was estimated as follows: 100 ft^3/hr — 400 ft^2 250 ft^3/hr — 400 ft^2 550 ft^3/hr — 400 ft^2 1,000 ft^3/hr — 800 ft^2 2,500 ft^3/hr — 2,000 ft^2 4,000 ft^3/hr — 2,800 ft^2 Cost of \$35 per ft^2, a 20% overhead construction fee is added to the calculated cost.	Additional space needed is author's assumption. Cost per ft^2 from Means Square Foot Costs 1984 p. 165.

VARIABLE COSTS

Integrated and Free Standing Facilities

Supplies	2% of facility cost	Author's assumption.
Utilities	2% of facility cost, plus \$.112 per ft^3 of refrigerated warehouse space.	Author's assumption. Utilities for refrigerated warehouse from Hudson, 1984.
Variable maintenance	65% of total maintenance (total maintenance estimated at 1.5% of facility cost).	Industry sources.
Hourly labor	Annual Salaries: Shift supervisor and plant operator: \$30,000 + \$9,000 for fringes = \$39,000 for 2nd and 3rd shift. Plant operator: \$18,000 + \$5,400 for fringes = \$23,400 for 1st shift.	Estimated from information provided by the Office of Wages and Industrial Relations, BLS, and industry sources.

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Budget Item	Formulae and Assumptions	Source
Hourly labor (cont'd)	Material Handler: $15,000 + $4,500 for fringes = $19,500 for each worker per 8-hour shift. Number of handlers needed estimated for six throughput levels (see Appendix B.) (No provision is made for wage differentials for second and third shifts or weekend work. When irradiator is operated 7 days a week, fixed and variable labor costs are adjusted accordingly).	

Annualized Fixed Costs

The capital recovery factor was used to estimate the levelized annual charge to recover the original investment (purchase price), plus the opportunity cost of the money spent to buy the asset, over the useful life of the asset. Asset assumed to have no salvage value.

$$\text{Annual charge} = K \times \frac{i(1+i)^n}{(1+i)^n - 1}$$

where:
K = original investment
i = interest rate (assumed to be 11.75%)
n = number of years of useful life

The useful lives for capital assets were assumed to be 15 years for initial ^{60}Co loading; 25 years for buildings and biological shielding; and 10 years for machinery.

The other fixed costs were treated as follows:

land	11.75% of investment
working capital	11.75% of investment
^{60}Co replenishment fixed maintenance insurance and taxes salaried employees	current cost items

$$\text{Unit cost in \$/lb.} = \frac{\text{total variable cost} + \text{total annualized fixed cost}}{\text{throughput per year in lbs.}}$$

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APPENDIX D. Number of Product Handlers Needed for Six Sizes of Irradiators

Hourly throughput (ft^3)	pallets/hr. 1/	worker/hr. needed per pallet	no. of handlers needed per shift to run irradiator 4/	no. of handlers needed to unload trucks 5/	total no. of handlers needed per day
100 (hand)	2	.26 2/	1	.3	3.3
250 (hand)	5	.20	1	.6	3.6
500 (hand)	7	.20	2	1	7
1,000 (palletized)	12	.105 3/ × 1	3	2	11
2,500 (palletized)	29	.103 × 2	5	6	19
4,000 (palletized)	40	.103 × 2	7	7	28

1/ Although the ft^3 per pallet differs between products and shipments, I assumed one pallet = 40" × 40" × 70" = 140,700" or approximately 82 ft^3 (Source: APS marketing association, 1976). Pallets/hr. rounded up to next whole pallet.

2/ Source (with modifications): Table 6 - "Labor and equipment time and cost to unload 900 hand-stacked cartons of fresh tomatoes and move to storage" in Mangelli, Hat, 1982, p. 15.

3/ Source: Table 8 - "Labor and equipment time and cost to unload 900 palletized cartons (10 pallets) of fresh tomatoes and move to storage" in Mangelli, 1982, p. 17. The entry 1 or 2 handlers are needed for the depalletization).

4/ Number of product handling needed per shift rounded up to next whole person.

5/ See Appendix C for calculations. Trucks unloaded during 1 shift.

APPENDIX C. Product Handling Machinery Costs for Six Sizes of Irradiators

Hourly Throughput (ft^3)	Truckloads per day 1/	Truckloads per hr. 2/	Workers/hr. needed per truckload 3/	No. of handlers needed per day to unload trucks 4/	Forklift cost 5/ $	Palletizer cost 6/ $
100 (hand)	2.3	.3	.93	.3	30,000	0
250 (hand)	3.5	.4	.93	.4	30,000	0
550 (hand)	8.2	1.0	.93	1	30,000	0
1,000 (palletizers)	14.0	1.8	.93	2	30,000	168,000
2,500 (palletizers)	33.8	4.2	.93	4	45,000	272,000
4,000 (palletizers)	53.7	6.7	.93	7	60,000	293,000

1/ Truckloads per day = (no. of pallets per hr. x 24 hrs.) ÷ 10 pallets per truck.
2/ Trucks arrive and are unloaded during one 8-hr. shift.
3/ Source: same as footnote 3 of Appendix B.
4/ For largest irradiators, number of handlers needed rounded up to next whole person.
5/ Cost of forklift is $15,000 each.
6/ A semi-automatic depalletizer can handle about 24 pallets per hr. and requires one handler. The installed cost of the machine plus roller conveyor is assumed to be $84,000. An automatic palletizer can handle many more pallets per hr. and does not require a handler. The price of an automatic palletizer varies with its speed. The costs of the palletizers used in this analysis were assumed to be $84,000 for 1,000 ft^3/hr., $104,000 for 2,500 ft^3/hr., and $125,000 for 4,000 ft^3/hr. Source: Bobbie Poppel, Systems Manager for Columbia Machines, Vancouver, Washington.

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VI. MACHINE SOURCES OF RADIATION

In addition to gamma radiation from radioisotopes, electrons and X-rays from electron accelerators can be used as energy sources for food irradiation applications. A variety of machines are available ranging from small self-shielded, in-line units to larger machines requiring thick concrete shielding similar to the irradiation chamber in a gamma facility.

Electron accelerators are currently used for dozens of industrial applications including treating the insulation on wire and cable, cross-linking plastic food wrap, and curing high gloss coatings on paper and scratch-resistant coatings on magnetic tape. However, machine-generated radiation is not yet used to treat foods in the United States. The only commercial food use of machine radiation at this time is the two electron accelerators used to disinfest grain at a Russian port (see chapter IX). Experimental work on machine sources of radiation to treat food and feed is being conducted in several countries.

High energy electrons are produced when electrons emitted from a filament or cathode are accelerated by an electric field in a vacuum a tube. This beam of electrons then passes through an alternating magnetic field where it is "scanned" so it can emerge through a thin metallic window in a fan-shaped configuration; or the electrons may be unscanned and applied directly to the product after emerging from the window.

The beam power, expressed in kilowatts (kW), determines the amount of product that can be treated and at what dose. Typical power levels for these machines lie in the range of 10 to 20 kw for industrial linear accelerators to 200 kw for the lower voltage machines.

The energy level of the electrons (or voltage of the accelerator), expressed in electron volts (eV), determines their penetration in the irradiated material. Electrons can not be used on food products at energies much above 12 MeV (million electron volts) because of the possibility of induced radioactivity (Farrell, 1981, p. 1786). 1/ The Food and Drug Administration (FDA) does not allow use of electron accelerators on foods at energies above 5 MeV (21 CFR 179.24). However, FDA has proposed new regulations which would allow the use of accelerators producing a beam of up to 10 MeV (see chapter VIII).

Benefits of Machine Sources

One of the beneficial characteristics of machine sources is their ability to be turned off when not in use or when maintenance is required. Radioisotopes, on the other hand, are continuously decaying and giving off radiation. With machines, no radioactive materials must be transported from an

1/ In comparison, the energy levels of gamma rays from cobalt-60 are 1.17 and 1.33 MeV. Cesium-137 emits a gamma ray of 0.66 MeV (Goresline, 1970, p. 8). One MeV equals 1.6×10^{-6} erg (ibid, p. 7).

encapsulation location to the irradiator as with the gamma facilities. The direction of the electron beam can be channeled helping to improve the net utilization efficiency of the source to levels of 40 to 60 percent, compared to 15 to 30 percent for cobalt-60 (Deitch, et. al., 1972, pp. 72-73).

Machine sources of radiation are capable of treating large quantities of materials per unit of time because of their high dose rates. Radioisotopes have dose rates of around 20,000 rads per minute, while machines are capable of dose rates of 60 million rads per minute or more (Rutt, 1984, p. 2). The conveyor system must be designed to move product quickly through the beam. An intense, low-energy radiation source would overprocess the surface of a food while underprocessing its interior. Thus, an appropriate match of product thickness and conveyor speed to machine energy and power is crucial.

Penetration Limitation and X-rays

Electron beams at a level of 10 MeV can only penetrate about 3 inches into a food, if both sides are treated (table VI-1). Treatment from both sides more that doubles the useful depth of penetration possible with treatment from one side because of the overlap of the beam power. This 3-inch penetration limits electron accelerators to surface treatment of foods or treating products in individual thin packages or a shallow stream of small particles like grains and powders.

Table VI-1. Maximum Penetration by Electron Beams Through Water 1/

Energy	Treatment on one side		Treatment on both sides
	To end of range	Useful depth[2]	Useful depth[2]
MeV	inches		
1	.16	.11	.28
2	.32	.22	.57
3	.50	.35	.83
4	.69	.48	1.17
5	.87	.61	1.51
6	1.06	.76	1.84
7	1.26	.88	2.17
8	1.48	1.01	2.54
9	1.67	1.14	2.84
10	1.87	1.26	3.17

1/ To obtain the penetration depth in different food products multiply the numbers in the table by the ratio of the density of water (1 gm/cm^3) to the density of the food item (Brynjolfsson, 1973, p. 19).
2/ The dose at the backside of the sample is the same as at the front side. Useful depth provides a more practical limitation than the end of range maximum.
Source: Deitch, et. al., 1972, p. 70. Data supplied by Ari Brynjolfsson, Chief, Radiation Sources Division, U.S. Army Natick Laboratories, Natick, Massachusetts.

The penetration limitation of electron beams can be overcome by converting the electron beams into x-rays or bremsstrahlung radiation. X-rays are produced when high energy electrons strike a metal target, such as tungsten. At 3 MeV or above, the penetration of x-rays is equivalent to that of cobalt-60 gamma rays (Deitch, et. al., 1972, p. 71). Much of the energy, however, is lost in the form of heat when electrons are converted to x-rays. The heat can be removed by flowing water through the converter plate (Lagunas-Solar and Matthews, 1984, p. 7). This low conversion efficiency increases the machine costs and power requirements for irradiation by x-rays compared with direct electron beam treatment. The efficiency of this conversion depends on the target material and the electron energy (Goresline, 1970, p. 13). Using tungsten as a target material and electrons at a energy level of 5 MeV, the percent of beam power radiated in a forward direction, and hence useful for processing, is 8 percent (table VI-2). The FDA is currently proposing to allow x-rays to be used to irradiate food, but only from machines operated at energy levels up to 5 MeV (49 FR 5722). This technique offers deeper penetration and therefore expanded uses, but has not been technically proven yet, and questions remain about the possibility of inducing radioactivity.

Table VI-2. Conversion Efficiency for X-rays with Tungsten as the Target Material

Energy of Electron Beam	Conversion Efficiency	Forward Efficiency
MeV	percent	percent
3	4.8	3
5	10.1	8
10	23.4	19

Source: Matthews, 1985.

Comparison With Cobalt-60 Facility

Small machines at energy levels of 150-300 keV are encased in lead and can be inserted directly into an existing processing line (Nablo, 1984, pp. 2-11). These self-shielded machines are only capable of limited penetration (.02 inch through water). Manufacturers of these machines are studying its suitability for treating food particulates and powders.

Industrial manufacturers of electron beam machines are now offering 10 MeV units in the 10 to 20 kW range. This kW power is equivalent to 1.1 to 2.2 million curies of cobalt-60. 2/ Larger machines and x-ray producers above 500 keV need concrete shielding similar to the gamma facilities, although no storage pool of water is needed (see figure VI-1).

2/ This conversion is based on 1 million curies of cobalt-60 producing about 15 kW of power, and assuming net utilization efficiencies of 30 and 50 percent for cobalt and machine irradiators, respectively.

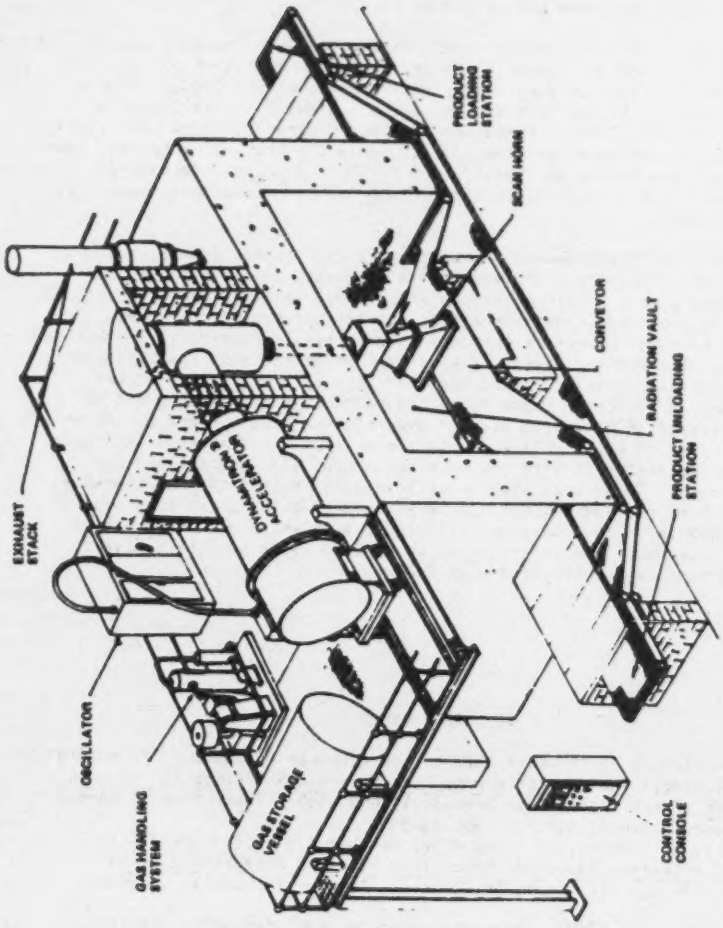

Figure VI-1. Drawing of typical electron beam accelerator (Courtesy of Radiation Dynamics, Melville, New York).

Both types of facilities would need conveyor systems, auxiliary systems for ozone and heat removal, and trained personnel to operate the system, perform quality control functions, and load and unload the conveyor. Maintenance costs for the machine source are expected to be higher because more highly skilled technicians are needed. In addition, the machine sources require electricity to power the accelerator.

The capital costs of electron accelerators vary with energy level and power. As energy level and power increase, so does the cost of the machine. Cost estimates for electron accelerator units range between $900,000 for a 1.5 MeV / 75 kW machine and $2.5 million for a 4.5 MeV / 150 kW linear accelerator (O'Donnell, 1985). Costs for shielding, other building space, and material handling equipment must be added. Costs for the self-shielded, lower energy machines are approximately $500,000 for 100 kW units. Operating costs for both types of machines would include labor, maintenance, supplies, and electric power.

Physicists and engineers in the United States, Canada, France, United Kingdom, and other countries are working on improving machines to increase their available power, x-ray conversion efficiency, reliability and dose uniformity. A prototype induction linear accelerator has recently been built at the Lawrence Livermore National Laboratory (Lagunas-Solar and Matthews, 1984, p. 10). The modular design of this type of accelerator enables a series of accelerating stages to be linked together to boost the voltage of the electron beam. Advances in magnetic switch technology have made these accelerators capable of very high average power in the megawatt range. Scientists at the University of California at Davis are working with Lawrence Livermore scientists to determine if this new machine concept has applications for irradiating food. These very high power levels may exceed the requirements for electron beam processing, but may be advantageous for x-ray treatment of bulk foods because of the low power efficiency with which electrons can be converted to x-rays. This experimental work may provide an alternative to radioisotope sources for treating bulk foods.

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VII. ALTERNATIVES TO IRRADIATION

Earlier chapters discussed the potential of irradiation for extending shelf life, protecting public health, and improving product characteristics. However, in many instances, irradiation is not the only method by which these benefits can be achieved. During the four decades of irradiation research and development, other advances were being made in the areas of disinfestation and preservation processes. Alternatives to irradiation range from rearing trichinae-free hogs to improved storage and packaging technologies. Irradiation and other techniques and practices may not be direct substitutes because each technology has characteristics that influence its technical and economic feasibility. Irradiation must compete with other techniques both in terms of cost and acceptability to food safety regulators, processors, retailers, and consumers. This chapter describes selective examples of other technologies with which irradiation must compete.

Methods for Extending Shelf Life

Food technologists continue to develop ways to lengthen the shelf life of perishable foods. Three approaches are highlighted below.

Controlled Storage

Refrigeration is a common method used to lengthen the marketing season of many fruits. Apples, pears, grapes, lemons, and tree nuts are commonly stored for long periods (Ryall and Pentzer, 1982, p. 368). Controlled atmosphere storage is used in the United States to store apples for year round marketing. Controlled atmosphere storage rooms combine refrigeration with an atmosphere higher in carbon dioxide (CO_2) and lower in oxygen than normal air. This environment slows respiration and ripening processes which cause softening, yellowing, and other undesirable qualities. Sub-atmospheric pressure (hypobaric) storage is a type of controlled atmosphere storage that reduces the atmospheric pressure on fruits and vegetables. Respiration is slowed down and many fungi are suppressed (Salunkhe, et. al., 1984, p. 200).

Packaging materials such as polyethylene bags retard respiration and thus increase shelf life of fresh fruits and vegetables. Modified or controlled atmospheres can be combined with airtight packages to extend the shelf life of fresh meat, too. For instance, Princeton Packaging Inc. has developed a hermetically sealed, controlled atmosphere package for fresh retail meats (Rice, 1985, p. 121). Under refrigeration, the 3-layer package can protect ground beef for 10 days and solid beef cuts for 3 weeks. Wilson Foods Corporation has petitioned USDA for approval to use a controlled atmosphere packaging system to increase the shelf life of fresh pork (Food Chem. News, 1985, p. 23).

Edible Coatings

Another shelf life extension technique is to apply an edible coating to fresh produce, nuts, and meats. Several versions of this coating exist. One material, called Pro-long, is a powdered mixture of lipids and a poly-

saccharide (fats and a carbohydrate) that is dissolved in water and then applied to certain fruits and vegetables (Lowings and Cutts, 1982, p. 53). Upon drying, the mixture forms a semi-permeable gas barrier which reduces metabolic rate and water loss. "Pro-long" was developed in the United Kingdom for use on bananas and then extended to fruits such as apples, pears, mangoes, limes, avocados, and plums (Lowings and Cutts, 1982, p. 54). The treatment also reduces susceptibility to chill injury in bananas (irradiation can have the opposite effect) and increases resistence to some fungal rots in apples, pears, and plums.

Natural edible coatings have also been developed in the United States. One compound, produced by combining corn protein with special vegetable oils can be used on a variety of food ingredients such as fruit pieces, chocolate chips, and nuts (Andres, 1984a, p. 48-49). The coating helps retain desirable moisture within the food and control external moisture, preventing growth of molds and microorganisms. Research with pecans has shown that the treatment can prevent rancidity and oxidative staling, increasing shelf life. In a similar vein, lemons shrink-wrapped in plastic coating do not dehydrate like unwrapped lemons and can be stored for six months or more (Bovard, 1985, p. 30).

Edible coatings exist for use on meats, too. One coating claims to extend the shelf life of refrigerated beef up to 50 days and of lamb up to 70 days (Andres, 1984b, p. 58) The coating is a tasteless, oily liquid manufactured from vegetable oil that is applied in conjunction with Cryovac packaging. It preserves good color and reduces weight loss by retaining desirable juices. The same company has developed coatings for sausage and cheese products.

High Pressure Fish Washer

A fish washer that uses high pressure water to reduce the number of spoilage bacteria and thereby extend shelf life has been designed by George Flick at Virgina Polytechnic Institute and State University in Blacksburg, Virginia. Instead of a 4 to 6 day shelf life, fish could remain fresh for 11 to 17 days (Flick, 1985). The cost of the process is expected to be a few cents per fish when used on a commercial scale, but the final cost has not been determined yet. An important cost factor is whether the water can be filtered and reused. Additional shelf life extension may be possible by adding sanitizers to the wash water to further lower bacterial counts on fish or by combining the fish washer with a modified atmosphere (CO_2 or nitrogen) in the package. However, a shelf life beyond 15 to 16 days is not valued by the industry (Flick, 1985). Another food safety concern with significantly increasing shelf life through modified atmosphere packaging is the potential for C. botulinum type E organisms to produce toxin before the fish spoils if proper temperature control is not maintained during storage (Eklund, 1982, p. 111) (see discussion in chapter II).

VII-3

Fumigation Alternatives

Chemical fumigants are commonly used to control insect infestation in harvested grains, fruits, and nuts. Fumigant gas is released into a sealed structure holding the commodities, killing insects and eggs for up to a year. Chemical protectorants can be mixed with or sprayed on grain as it is loaded into storage. Many people are dissatisfied with chemical treatments because of the potential danger they pose for workers administering the gas or chemical and for consumers if residues remain. Alternative treatments include using oxygenless air, cold storage, or heat treatment to kill insect pests. The Australians treat some of their stored grain with CO_2. Provided the grain silo is properly sealed, its contents can generally be stored for four months without infestation (Boland, 1984, p. 15).

Control Options for Pathogens in Meat and Poultry

Pathogens in food depend upon the initial contamination of the raw product; reduction in their numbers with canning, freezing, salting or other processing operations; and post-processing changes in pathogen numbers depending upon temperature and length of storage, handling, and other conditions (Mossel and Stegeman, 1985). Thus, control procedures can be aimed at reducing or eliminating raw product contamination, improving processing effectiveness, or developing more effective post processing methods of pathogen control.

Salmonella and Campylobacter Control in Chickens

Irradiating chicken appears to offer significant health protection against diseases caused by Salmonella and Campylobacter. Other means need to be considered for preventing or controlling these bacterial pathogens. Health officials worldwide generally agree that Salmonella contamination cannot be eliminated, and can be reduced to low levels only by preventive measures at each stage of production and processing. These measures include improvements in hygiene, management, and equipment from the feed mill through the consumer (Snoyenbos, 1985). There is no easy answer. Some of the most commonly mentioned improvements, including those in use and those still on the drawing board, are discussed below.

1) Produce animal feed ingredients that are close to salmonella-free by heat pelletizing. Irradiation of feed and ingredients, as opposed to the final product, is another technique. Israel has built a demonstration facility using a 1.5 MeV electron beam accelerator to irradiation-sterilize 40 tons of pelletized feed per hour (Klinger, et. al., 1985). Salmonella-free feed is probably not an easily attainable goal because of post-processing environmental contamination through the air, by rodents, and even insects. Another cause of Salmonella proliferation in animals can be feed additives which sometimes promote Salmonella persistence in animal intestines and Salmonella shedding in fecal matter (Snoyenbos, 1985, pp. 90 and 319).

2) Maintain good farm practices to prevent cross-contamination during production: use Salmonella-free eggs, sanitize the chicken house in between flocks, prevent rats and mice (common carriers of salmonellosis) from entering the chicken house, and sterilize crates carrying chickens to slaughter.

3) Alter the procedures at the beginning of the slaughter line where chickens are defeathered by a combination of a hot water bath to loosen the feathers and a machine with rubber fingers that plucks the feathers. Both are potent sources of cross-contamination from one bird to others down the line. Several improvements have been suggested, although none have been perfected: adding acetic acid (vinegar) to the scald tank to kill Salmonella and other pathogens in the common water bath; replacing the common scald tank with temperature controlled steam scalding or some other form of individual carcass washing [1]; using ultrasonification (high energy sound waves) to make the poultry feathers drop off; and adding a poultry squeezer to squeeze out intestinal contents before they can contaminate the scald tank. This squeezer would also reduce the possibility of intestinal breakage during evisceration.

4) Alter procedures at the end of the slaughter line such as chlorinating the chill water to kill Salmonella [2]; adding lactic acid, sorbate, or some other acid to packaged poultry to kill some of the Salmonella or at least keep them from multiplying; eliminating the water in packages which is a source of cross-contamination in the kitchen; and monitoring for Salmonella on the production line (which will be more practical as more rapid detection tests become commercially available).

5) Inform commercial food handlers and consumers about the importance of maintaining very low refrigeration temperatures to reduce bacterial growth, procedures to avoid cross-contamination to other foods, and the importance of cooking chicken until it is well done.

A Canadian researcher, Leo Curtin, has estimated one year benefits and costs for eleven Salmonella control procedures in poultry (table VII-1). The one year time horizon may have biased the results toward low capital investment projects such as education of the food preparer at home or in the commercial sector. Still the results show benefits to be greater than costs for seven Salmonella control options. While Curtin's study is pathbreaking, it would be interesting to compare the results against a study using a longer time horizon and considering various clusters of options to determine the "optimal" package of control options.

Trichinae Control in Hogs

Options for reducing trichinosis can occur at three points in the food chain: improvements in farm management practices to eliminate trichinosis; slaughterhouse inspection to identify all carcasses and take them out of the food chain; and cooking, freezing, or irradiating all carcasses to destroy Trichinae. For decades the Europeans have used a trichniscope to identify contaminated carcasses and over time have virtually eliminated trichinosis in hogs. A recent fast tissue digest system has been developed to identify trichinae and costs only 7 to 10 cents per carcass (Murrell, 1985b). Another option is a blood test that identifies a Trichinae-infected hog. This test

1/ Steam scalding may also replace defeathering machines to some extent.
2/ A procedure used in some U.S. plants but not those exporting to Europe where several countries have outlawed chlorination of chill water.

Table VII-1. Benefit/Cost Comparison of Eleven Salmonella Control Options for Poultry in Canada, 1982

Control Option	B/C ratio a/
Education of the homemaker to prevent cross-contamination	12.0
Use of chlorine dioxide in chill water in poultry packing houses	10.3
Education of the food service sector to prevent cross-contamination	9.7
Adequate cleaning and disinfection of poultry crates	8.3
Clean up poultry processing industry	7.5
Irradiation of packaged fresh poultry	1.5
Clean rendered products which are ingredients in chicken feed	1.5
Clean-up and disinfection of the grower barns	.7
Sterilize feed to prevent Salmonella contamination	.6
Nurmi culture to increase the resistance of young chicks to Salmonella infection	.6
Production of clean hatching eggs and maintenance of a clean hatchery	.2

a/ These are static, one year benefit/cost ratios based primarily on expert opinion.
Source: Data from Curtin, p. 67.

is in the final stages of development and is expected to be inexpensive. Farm management options to break the Trichinae recontamination cycle include better control of rats around hog pens, reduction of hog cannebilism, and enforcement of garbage cooking regulations to assure the trichinae cysts are killed in garbage fed to hogs. The costs of irradiation (see cost chapter) are substantially greater than slaughterhouse inspection techniques such as the tissue digest which argues against irradiating hog carcasses.

Toxoplasma gondii Control Options

Several options have been suggested, but none rigorously studied:

- A public health prevention program aimed at pregnant women to caution them to cook meat thoroughly 3/ and to wash their hands after contact with meat, cats, and soil and before eating (Frenkel, 1981). Frenkel estimates perhaps congenital cases of toxoplasmosis could be cut by 50 percent with such an educational campaign.

- A screening program for pregnant women which would detect those with active infections and then counsel either abortion or treatment with somewhat toxic drugs (Fayer and Dubey, 1985, p. 59). This approach has major drawbacks because it would expose some uninfected babies to the toxic drugs or result in abortion of some healthy fetuses (Wilson and Remington, 1980). Furthermore,

3/ Meat needs to be heated to 60°C (140°F) for 20 minutes (Dubey, 1980, p. 1207). A rare roast only reaches 140°F--it does not stay at that temperature for 20 minutes.

the cost of the screening [illegible] may be about equal to the present cost to society to care for babies born with congenital toxoplasmosis.

* Control of toxoplasmosis in cats on farms raising food animals either by vaccination of cats, strict dietary control for cats (no hunting rats and mice), or elimination of cats from these households.

None of these three options will be 100 percent effective in eliminating toxoplasmosis. More risk/cost study is needed to determine the relative benefits and costs, although the prevention program aimed at pregnant women may have relatively high net benefits to society.

Exposure Control Options

Yersinia enterolitica is a pathogen identified under USDA's Food Safety and Inspection Service (FSIS) federal inspection. Heavily contaminated carcasses are removed from the food chain, and lightly contaminated carcasses are passed for freezing or cooking to kill the Yersinia cells ("Meat and," 1979, p. 11). Both these options cost time and money. Also, cooking or freezing alters the appearance of the meat and restricts the use; cooked meat cannot be sold as fresh meat, and previously frozen meat may "weep" too much for use as steaks.

Improved Product Characteristics

Irradiation has also been discussed as a treatment for enhancing the quality of food and improving certain characteristics. Alternative processes to achieve desirable qualities continue to be developed. Below are a few examples.

A New Food Preservative

One of the benefits of irradiation is the potential as a substitute for chemical preservatives, such as sodium nitrite used in processed meat and poultry products. Researchers at USDA's Eastern Regional Research Center in Philadelphia have advanced a group of nontoxic food preservatives that replress bacterial growth, including S. Typhimurium, at concentrations one-thousandth of sodium nitrite (Anon., 1980, p. 30).

Improvements in Canning and Freezing

Proponents of irradiation are quick to point out how radiation sterilization of a product is less destructive to the texture, nutritional quality, color, and flavor than canning. However, processors have continued to refine thermal processing to shorten the heating time and thus reduce the stress on product quality. Aseptic processing uses the principle of rapid heating at

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[1] Since approximately 30 percent of women infected during pregnancy have no detectable signs of illness, blood tests of all pregnancy women must be undertaken to determine exposure and infection (Wilson and Remington, 1980, p. 360).

high temperatures which has a greater destructive effect on bacterial spores than on food quality (Bean, 1981, p. 95). Direct flame heating applied to the outside of a rotating metal can results in extremely short processing times. Researchers at the University of California, Davis are testing a new approach that requires less liquid, salt or sugar; permits packaging low-acid foods; and reduces energy requirements by 20 percent (Anon., 1984a, p. 15).

Refinements have also been made in freezing techniques. Rapid surface freezing of fruit protects the product from handling damage and prevents loss of juices (Morrison and Ellis, 1984, p. 60-61). A freezing process developed by Rich Products Corporation isolates and controls the moisture content in food inhibiting the formation of ice crystals and creating an unfavorable environment for bacterial growth (Anon, 1982). A new freeze-drying process developed by Beatrice allows freeze-dried vegetables to rehydrate faster than air-dried vegetables (one of the benefits irradiation offers) (Anon., 1984b, p. 35).

Cost Competitiveness

An important consideration in an assessment of the economic feasibility of any new process is how the treatment cost compares with other methods. If irradiation is being considered to replace an existing process with which processors and consumers are satisfied, it must demonstrate significant quality-enhancing properties or cost savings for a firm to abandon existing equipment and/or processing methods and build and operate an irradiator. On the other hand, if irradiation is the only available alternative, its cost competitiveness is no longer an issue. How the firm's decision is whether it can generate enough revenue from selling the irradiated product to recoup the expense of irradiation and other production costs.

The purpose of this study was not to demonstrate irradiation's economic feasibility in comparison to other technologies. However, to give the reader some idea of other treatment costs, table VII-2 lists cost estimates for disinfestation techniques and trichinae control which the authors came upon during this study. It can be misleading to compare the estimates in table VII-2 with each other, or with the irradiation costs in chapter V, because of different volumes analyzed, the varying time frames used, and different approaches and assumptions used by each researcher. Also, some treatments (including irradiation) may involve supplementary practices or handling steps not included in these estimates.

Table VII-2. Selected Cost Estimates for Disinfestation and Trichinae Control

Purpose and Commodity	Method Used	Volume Analyzed	Year of Study	Treatment Cost	Source and Remarks
		million lbs.		cents per pound	
Insect Control:					
Stored Raisins	Methyl bromide	1.6	1980	0.11	Gardner, et. al., 1982, p. 11 1/
	Phosphine	1.6	1980	0.22	Ibid.
	Low-Oxygen Atmosphere	1.6	1980	0.21	No heat recovery }
				0.17	80-90% heat recovery } Ibid., p. 12
	Nitrogen Atmosphere	1.6	1980	0.47	On-site nitrogen production Ibid., p. 14
				0.54	Trucked nitrogen Ibid., p. 13
Hawaiian Papaya	Chemicals	?	1984 (?)	2.3	Moy, 1985, p. 66
	Ethylene dibromide	34 (total)	1984	0.15	Secretary of Agriculture, 1984, p. 21
	Double hot dip	23.8 (total)	1984	0.15 to 0.20	Ibid.
	Phosphine	34 (total)	1984	0.38 to 0.75	Ibid.
Florida Grapefruit	Ethylene dibromide	319.5 (total)	1984	0.24	Ibid. p. 18
	Cold treatment	240 (total)	1984	0.83 to 1.2	Ibid.
	Methyl bromide	80 (total)	1984	0.31 to 0.38	Ibid.
	Phosphine	80 (total)	1984	0.8 to 1.5	Ibid.
Grain	Carbon dioxide	?	1985	0.023 to 0.03	Includes cost of sealing storage structure. Boland, 1985
	Contact insecticides	?	1985	0.005 to 0.033	Ibid.
	Phosphine	?	1985	0.017 to 0.034	Includes cost of sealing storage structure. Ibid.
Trichinae Control: Pork	Freezing	?	1977	0.35 to 3.2 (on site) 2.3 to 3.4 (off site)	Francke, et. al. 1977, p. 1 Range results from the variety of methods used.
	Tissue digest for detection	large volume slaughterhouse	1985	0.04-0.06	Murrell, 1985b

1/ These estimates are for six treatments per season and do not include the cost of building a storage stack.

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VIII. REGULATORY ENVIRONMENT

Several U.S. Federal agencies have regulatory roles in food irradiation. The initial regulator that a processor interested in irradiating food or animal feed must satisfy is the Food and Drug Administration (FDA) of the U.S. Department of Health and Human Services. Processors must comply with FDA's regulations prescribing safe use of radiation on foods or obtain approval through the petition process for additional uses. If a processor wishes to use radiation to treat meat, poultry, or egg products, the processor must also petition USDA for permission. A facility using radioisotopes as the radiation source must be licensed by the U.S. Nuclear Regulatory Commission or an agreement State. If the radiation is machine-generated, the machine must comply with FDA performance standards. The operator of the facility must comply with State regulations, if applicable, and with Occupational Safety and Health Administration limits for worker exposure to radiation. Casks in which radioisotopes are shipped must comply with the Department of Transportation's safety requirements and design criteria and must be reviewed by the Nuclear Regulatory Commission.

FDA Approval Required

Commercial irradiation is legal for only a few foods in the United States today. Spices for ingredient use are the only foods irradiated, and the volumes are small. A rule proposed by FDA in February 1984 would allow the use of low doses of radiation to delay ripening of fresh fruits and vegetables and to kill insects that infest food. Irradiation of foods for commercial sale is governed by the Federal Food, Drug, and Cosmetic Act, the basic food and drug law of the United States, 21 U.S.C. 301-392 (Takeguchi, 1983, p. 213). 1/ A 1958 amendment to this Act specifically includes "any source of radiation" intended for use in processing or packaging food in the definition of a food additive (21 U.S.C. 321). The Food Additives Amendment of 1958 (P.L. 85-929) requires processors to comply with FDA regulations prescribing safe use of radiation to treat foods or processors may submit a food additive petition with data supporting an amendment to these regulations (21 U.S.C. 348). The Federal Food, Drug, and Cosmetic Act states that food is considered adulterated if it has been intentionally irradiated, unless there is a regulation for such use (21 U.S.C. 342).

Current FDA Regulations

Table VIII-1 lists the foods for which FDA has granted approval to irradiate. In the early 1960's, FDA approved the use of radiation at doses between 20 and 50 krads (.2 to .5 kGy) to control insect infestation in wheat and wheat flour and doses of 5 to 15 krads (.05 to .15 kGy) to inhibit sprouting of white potatoes. Neither of these applications has ever been

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1/ In the Federal Food, Drug and Cosmetic Act, "food" is defined as articles used for food or drink for man or other animals, chewing gum, and all ingredients in such articles (21 U.S.C. 321). U.S.C.--United States Code; P.L.--Public Law; CFR--Code of Federal Regulations; and FR--Federal Register.

Table VIII-1. FDA Approvals and Proposals for Irradiating Foods
As of December 1985

Food	Dose	Application	Year Approved
	krads (kGy)		
Wheat and wheat flour	20 to 50 (.2 to .5)	Control insect infestation	1963
White potatoes	5 to 15 (.05 to .15)	Inhibit sprouting	1964
Spices and dried vegetable seasonings	Up to 1,000 (Up to 10)	Control microbial contamination	1983
		Control insect infestation	1984
Dried enzyme preparations	Up to 1,000 (Up to 10)	Control insect and microbial contamination	1985
Fresh pork	30 to 100 (.3 to 1)	Control Trichinella spiralis	1985
Fresh fruit and vegetables	Up to 100 (Up to 1)	Inhibit growth and maturation	Proposed
Food	Up to 100 (Up to 1)	Insect disinfestation	Proposed
Spices and dried vegetable seasonings	Up to 3,000 (Up to 30)	Microbial disinfection	Proposed

used because of the availability of less expensive and easier to use chemicals. In 1963, FDA approved a petition submitted by the Department of the Army for irradiation of canned bacon at doses of 4,500 to 5,600 krads (45 to 56 kGy) (28 FR 1465). However, in 1968, FDA revoked the approval after additional data from animal feeding studies raised doubts about the safety of irradiated bacon (33 FR 15416). At that time, the Army withdrew a 1966 petition for irradiated ham because it was based on the same data as the bacon petition (33 FR 11098).

In July 1983, FDA approved gamma radiation to control microbial contamination in dried spices and dehydrated vegetable seasonings (onion and garlic powders) at doses up to 1,000 krads (10 kGy) (48 FR 30613). In June 1984, this approval was expanded to cover insect infestation as well (49 FR 24988). Only a small portion of U.S. spices are currently irradiated; the remainder are treated primarily with ethylene oxide. As the rules governing worker exposure to ethylene oxide become stricter, spice manufacturers must look for alternative ways to decontaminate spices, including irradiation.

Two uses were approved in the summer of 1985. Dried enzyme preparations can be irradiated at doses up to 1,000 krads (10 kGy) for insect and microbial control (50 FR 24190). In July, FDA approved the treatment of pork carcasses and fresh cuts of pork at doses between 30 and 100 krads (0.3 to 1 kGy) to control Trichinella spiralis (the organism that causes trichinosis) (50 FR 29658-9). Irradiation's use on pork must also be approved by USDA (see subsequent section on FSIS approval for meat and poultry uses).

Under existing FDA regulations, retail packages of irradiated foods must be labeled "treated with ionizing radiation" or "treated with gamma (or electron) radiation." Wholesale packages and invoices or bills of lading for bulk shipments must add the phrase "-do not irradiate again" (21 CRF 179.22/24).

FDA also has rules governing what packaging materials can be irradiated, and at what doses, for prepackaged foods (21 CFR 179.45). For example, if a processor wanted to irradiate pork chops packaged in consumer-ready trays, the packaging materials (tray and overwrap) must be on the list of approved materials. An informal review by a food technologist at Michigan State University's School of Packaging found that one commonly used film wrap and a few new packaging materials are not on the approved list (Giacin, 1984). FDA would need to approve the irradiation of these materials before they could be used.

Findings of the Bureau of Foods' Irradiated Food Committee

Congress included irradiation in the food additive definition to be sure that the process was safe by requiring adequate safety tests. For additives that may become a large portion of the diet, wholesomeness feeding studies are performed to determine that the additive is microbiologically, nutritionally, and toxicologically safe (Takeguchi, 1983, p. 215). In traditional animal feeding studies, laboratory animals are fed exaggerated amounts of the test substance to provide a safety factor when applying the results to humans. Feeding animals enough of a specific irradiated food item to obtain a 100-fold safety factor is close to impossible because it will severely effect the nutritional balance of their diets (49 FR 5715).

This problem was recognized by the FDA's Bureau of Foods' Irradiated Food Committee (BFIFC) in their assessment of FDA's policy on safety tests for irradiated foods. The Committee, therefore, recommended a series of well accepted, short-term mutagenic tests to detect toxic substances in foods irradiated at levels above 100 krads (1 kGy) (Brunetti, et. al., 1980, p. 18). The Committee stipulated that the tests must be performed using extracts of irradiated foods in which the concentration of radiolytic products is maximized. Radiolytic products are the chemical substances formed as a result of exposure to radiation. In addition to the mutagenicity tests, foods irradiated at doses above 100 krads must be evaluated in 90-day feeding studies in one rodent and one non-rodent species (ibid, p. 19).

Another issue raised by the definition of radiation as a food additive is whether safety data must be supplied for its use on each separate food item. Under the laws of radiation chemistry, foods of similar chemical composition would be expected to generate structurally similar radiolytic products (Brunetti, et. al., 1980, p. 22). This relationship makes it possible for regulators to extrapolate radiation chemistry data between similar foods. The BFIFC concluded that toxicological data obtained for a food item may be applicable for a chemically similar food irradiated under the same conditions (ibid).

One of the assignments of the BFIFC was to assess the safety of the radiolytic products formed when irradiation breaks certain chemical bonds and molecules reattach differently. Similar reactions occur during cooking, and the BFIFC found that 90 percent of the radiolytic products identified are natural components of food. After reviewing previous radiochemistry studies, the BFIFC concluded that irradiation at 100 krads (1 kGy) or less yields a total concentration of radiolytic products in food of 30 parts per million. The level of individual radiolytic products is difficult to detect and, hence, measure potential toxicity. The concentration of unique radiolytic products (compounds not found in the food before irradiation) would be on the order of 3 parts per million. The BFIFC concluded that this low level of unique radiolytic products means that food irradiated at 100 krads or less is wholesome and safe for human consumption (Brunetti, et. al., 1980, p. 16).

The BFIFC made a separate recommendation concerning foods that comprise less than 0.01 percent of the daily diet, such as spices. The Committee concluded that this category of foods could be safely irradiated at doses up to 5,000 krads (50 kGy) because of the extremely small amount eaten per person per day (Brunetti, et. al., 1980, p. 16). Also, scientists have found that the quantity of radiolytic products produced by irradiation is smaller in foods containing less water. Therefore, irradiation of spices, which contain little or no water, would yield a smaller quantity of radiolytic products than would moist foods. These recommendations formed the basis for FDA's current proposed rule discussed below.

FDA's Proposed Regulations

Up until now, permission to use irradiation on foods has been granted or denied in response to individual petitions submitted to FDA. However, FDA can also issue generic permission through Agency action.

On February 14, 1984, FDA published a proposed rule that would allow the use of irradiation to delay ripening of fresh fruits and vegetables and to kill insects that infest food (49 FR 5714-5722). Doses could not exceed 100 krads (1 kGy). FDA is also proposing to raise the maximum dosage for dried spices and vegetable seasonings from 1,000 to 3,000 krads (10 to 30 kGy). This proposed rule follows an advanced notice of proposed rule making and public comment period issued in March 1981.

FDA proposed expanding the sources of ionizing radiation for treatment of foods to include x-rays generated from machines operated at energy levels not to exceed 5 million electron volts. The proposed rule would raise the permitted energy level for electron accelerator machines from 5 to 10 million electron volts.

This same proposal contains regulations for firms irradiating food. Firms would be required to have "a qualified person with expert knowledge of radiation processing" develop a scheduled process specifying the dose range needed to achieve the intended effect. In addition, FDA has reserved the right to inspect the processor's records pertaining to the irradiated foods. These records will include the food treated, the lot number, the scheduled process, distribution of the irradiated food product, and date of irradiation. These records must be available for FDA inspection for 1 year beyond the shelf life of the irradiated food.

On the controversial issue of labeling, FDA reversed its earlier position stating: "The agency now believes that there is no need for a special label on irradiated foods because this proposal would limit the conditions of use of irradiation to those that have already been shown to be safe" (49 FR 5718). The proposal goes on to say, however, that FDA will continue to review new information on the labeling issue and welcomes comments on this area. FDA decided to retain the labeling requirement, "treated with ionizing radiation--do not irradiate again," for nonretail containers of irradiated foods and for the invoice or bill of lading used in shipping bulk foods.

In the proposed rule, FDA stated that the agency is currently reviewing studies to determine whether foods irradiated at doses above 100 krads (1 kGy) can be considered safe without additional toxicological studies for each food item. Studies under review include the wholesomeness studies of radiation-sterilized chicken initiated by the Army in 1976. These studies, submitted to FDA for their review in March 1984, consisted of a series of 20 animal feeding studies designed to assess the safety of irradiation-sterilized chicken (average dose of 5,900 krads or 59 kGy) in relation to mutations, tumors, reproductive effects, toxicity, and other safety concerns (Thayer, 1984, p. 355).

During the 90-day public comment period, FDA received over 4,000 comments. FDA must study these comments to be sure that the public's concerns about the proposed action are addressed in the final rule. At the time of this

report, FDA has not released a description of the composition of these comments nor has the final rule been issued. 2/

FSIS Approval for Meat and Poultry Uses

USDA's Food Safety and Inspection Service (FSIS) is responsible for the safety and wholesomeness of U.S. meat and poultry. Under the Federal inspection acts covering these products, they are considered adulterated if subjected to radiation, unless there is a regulation for such use pursuant to the food additives section of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 453, 601, 1033). Thus, FSIS can not authorize use of irradiation until FDA has approved its use for meat and poultry. However, FSIS can restrict the irradiation of products under its jurisdiction if the Agency feels the irradiation of these foods is not safe. Following FDA's approval of irradiation of fresh pork, FSIS has begun rulemaking procedures to add irradiation to their list of approved food additives (9 CFR 318.7).

A processor interested in irradiating federally-inspected pork carcasses or cuts would need to submit a description of the equipment, operating procedures (including how the dose will be controlled and verified), and labeling intentions for approval by FSIS. In addition, if the processor's facility is not already a USDA-inspected meat establishment, such as a contract irradiator, the facility would need to be approved by FSIS as a federally-inspected establishment (Gast, 1985). FSIS must consider whether irradiation treatment would alter the Agency's inspection procedures. Inspectors would need to be trained to regulate this new technology. The concerns of processing plant workers would also need to be addressed.

In the area of labeling, FSIS is not required to be in accord with FDA, although the Agencies generally try to avoid inconsistencies. FSIS has discretion not to require irradiated meat and poultry products to be labeled. FSIS can also choose the terminology it feels is appropriate and accurate. If FDA does not require labeling of consumer packages, FSIS could impose this requirement for meat and poultry products.

Federal versus State preemption is an issue which may be of concern to a processor interested in irradiating food. Meat and poultry plants that prepare products for interstate or foreign commerce must be inspected by FSIS and comply with Federal regulations. State laws for state-inspected plants must be at least equal to the Federal regulations. There are specific

2/ On December 12, 1985, HHS Secretary Margaret Heckler signed a regulation permitting irradiation of fruits and vegetables at doses up to 100 krads (1 kGy) and irradiation of herbs and spices up to 3,000 krads (30 kGy) (Anon., 1985). Under the regulation, manufacturers, food processors, and food retailers must label fresh fruits and vegetables that have been irradiated. Retail labels must include an international logo (see figure 1 in chapter IX) and the statement "PICOWAVED" or "PICOWAVED TO EXTEND SHELF LIFE" (ibid). The regulation does not become a final rule until it is published in the Federal Register following review by the Office of Management and Budget.

preemption provisions in the Federal meat and poultry inspection acts precluding States from taking certain actions with respect to federally-inspected establishments and products, although other State actions must be consistent with Federal regulations.

FDA has jurisdiction over interstate commerce of food other than meat and poultry products. 3/ However, FDA does not generally have jurisdiction over intrastate commerce, and there and no specific Federal preemption provisions in the Federal Food, Drug, and Cosmetic Act. One area where the preemption question is likely to be raised is retail labeling of irradiated foods. 4/

Quarantine Treatment

Another area where USDA regulates the use of radiation on foods is through the quarantine protocols of the Animal and Plant Health Inspection Service (APHIS). APHIS enforces quarantine restrictions to avoid the accidental introduction or spreading of animal or plant pests and diseases between agricultural areas. With the U.S. Environmental Protection Agency's cancellation of ethylene dibromide's use as a fumigant for fresh produce, APHIS has had to develop and approve alternative disinfestation methods that will achieve quarantine goals.

Irradiation's role as a disinfestation technique has been studied by USDA scientists since the 1950's (Engel, 1985, p.6). Research on irradiation of Hawaiian papaya to control melon fly and Mediterranean and Oriental fruit flies is sufficient for APHIS to prescribe a quarantine treatment level of a minimum of 15 krads (.15 kGy) absorbed by the insect larvae (Secretary of Agriculture, 1985). But FDA approval must be granted before this quarantine alternative can be used. Research on irradiation's suitability to control Mexican and Caribbean fruit flies in grapefruit is several years from completion.

Licensing of Facilities and Transportation of Isotopes

The other three Federal agencies that have a role in regulating food irradiation technology are the U.S. Nuclear Regulatory Commission (NRC), the Occupational Safety and Health Administration (OSHA), and the U.S. Department of Transportation (DOT).

Radioisotope Facilities

Facilities using a radioisotope, such as cobalt-60 or cesium-137, must be licensed by the NRC or an agreement state. Twenty-seven states have entered into agreements with the NRC allowing them to license and inspect

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3/ FDA has some concurrent jurisdiction over meat and poultry products after they have left a FSIS-inspected plant to determine whether they have become adulterated (Cipolla, 1985).

4/ In fact, the Health Committee of the San Francisco Board of Supervisors tabled a proposal on August 13, 1985 that would have required posting of signs for irradiated food products at the point of sale in the city and county of San Francisco (CFI, 1985, p. 2).

irradiators in their State, except those owned and operated by the Federal Government (Cunningham, 1984). The agreements provide that each state will use its best effort to maintain compatibility with NRC's program.

The regulations enforced by NRC and the agreement states are designed to protect both radiation workers in the facility and the general public. 5/ NRC does not address the quality of radiation-treated products, except to assure that they (including foods) remain free of radioactive contamination (Cunningham, 1984). Also, NRC does not assure the availability of radioisotopes used in irradiators. In order to receive a license, a facility must conform to regulations on source integrity, safety procedures, radiation protection programs, personnel qualifications and training, and safety design features. Facilities are also subject to inspection by NRC or State regulators. NRC has jurisdiction over the safe production, storage, use, transport, and disposal of radioactive materials.

In 1984 hearings before the Subcommittee on Energy Research and Production, Richard Cunningham, director of NRC's Division of Fuel Cycle and Material Safety, said that NRC is not planning to conduct any further safety-related research for irradiators. He went on to say that NRC looks to the private sector or other government agencies to conduct any research needed to demonstrate that new design concepts or equipment meet present radiation safety requirements (Cunningham, 1984).

DOT regulates the transport of radioactive materials and has specific safety requirements and design criteria for the casks that carry radioisotopes. These casks are also reviewed and approved by NRC.

Machine Facilities

Facilities using machine-produced sources of radiation are not under NRC's jurisdiction. FDA has authority over the manufacturer of the machine to ensure that the machine meets FDA's safety standards. However, FDA does not control facility safety and exposure in the workplace. In many States, the State health agency or a special commission regulates facility safety through a registration procedure similar to NRC's licensing arrangement. OSHA regulates worker exposure by setting maximum exposure levels. OSHA does not have any licensing authority, but can issue citations and levy fines when facilities are not in compliance with OSHA standards (Weiner, 1985).

5/ OSHA does not have any jurisdiction over worker exposure to radiation in facilities using reactor-produced radioisotopes as their radiation source. However, OSHA's current worker exposure levels are essentially the same as NRC's standards for maximum exposure to radiation.

Leasing of Cesium-137

The Department of Energy (DOE) has no regulatory role in food irradiation. Continuing a research interest of its predecessor agency, the Atomic Energy Commission, DOE sponsors research programs using radioisotopes. These food-related programs are discussed in Chapter X. DOE also produces small amounts of cobalt-60 and has limited supplies of cesium-137 which were recovered from reprocessing of spent nuclear fuel begun in 1974. DOE is making part of the cesium-137 supply available on a leased basis to private irradiation companies. This situation is discussed in chapter XI.

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the maximum absorbed doses permitted for each. [1] This approach has been replaced by the unrestricted use of irradiation on any food up to a maximum absorbed dose of 1,000 krads (10 kGy). The actual dose applied depends on the intended processing or public health purpose and the tolerance of the food to radiation. Lower doses are appropriate for many purposes. The Expert Committee left the door open to future approvals of higher doses by stating in the introduction to the standard that the 1,000 krad "value should not be regarded as a toxicological upper limit above which irradiated foods become unsafe; it is simply the level at or below which safety has been established" (Codex, 1984, p. vii).

Retail Labeling

In the 1983 standard, the Codex Alimentarius Commission reversed its earlier position by declaring the requirement for retail labeling of irradiated foods. Under the 1979 standard, retail packages of irradiated foods would have carried a statement indicating that they had been so treated. Where labeling was not feasible, for example with bulk foods, the consumer was to be informed of the treatment at the point of purchase (Codex, 1983, p.7). The current Codex standard requires that shipping documents contain the name of the irradiation facility, the date irradiated, and lot identification. Retail labeling of irradiated foods will be in accordance with the Codex General Standard for the Labelling of Prepackaged Foods (Codex, 1984, p.2).

Labeling of irradiated foods was one of the issues discussed at the March 1985 meeting of the Codex Committee on Food Labelling. The Food Labelling Committee decided that irradiated foods should be identified. However, since most countries are currently debating what type of identification is appropriate, the Committee did not stipulate what form the identification should take. The Committee limited the proposal to "A food which has been treated with ionizing radiation energy shall indicate on the label that treatment in close proximity to the name of the food" (McKay, 1985, p. 1). The Committee also recommended that irradiated ingredients be declared in the list of ingredients or indicated on the label. These recommendations were adopted by the Codex Alimentarius Commission at the July 1985 session, with the stipulation that after two years the labeling requirement will be examined to see if it has imparted trust.

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[1] In the 1979 Codex standard for irradiated foods, the following eight foods at their respective dose limits were approved for human consumption:

- chicken — 700 krad (7 kGy)
- papaya — 100 krad (1 kGy)
- potatoes — 15 krad (0.15 kGy)
- strawberries — 200 krad (2 kGy)
- wheat and wheat flour products — 100 krad (1 kGy)
- red and red flesh — 220 krad (2.2 kGy)
- onions — 15 krad (0.15 kGy)
- rice — 100 krad (1 kGy)

Source: Codex, 1984, p. 5-11.

Re-irradiation

Another area where the Codex Alimentarius Commission reversed its earlier position is the provision for re-irradiation. Re-irradiation was prohibited under the 1979 standard. The 1980 Expert Committee concluded that while foods should normally be irradiated only once, in certain circumstances repeated irradiation might be justified. Under the new standard, re-irradiation is allowed for the following foods: low moisture foods irradiated for insect control; food prepared from materials irradiated at doses around 100 krads (1 kGy); food containing less than 5 percent of irradiated ingredients; and foods where the full dose is applied in installments for a specific technological purpose (Codex, 1984, p.3). The cumulative overall average dose should not exceed 1,000 krads (10 kGy). Re-irradiation within this dose would not be harmful, provided that nutritional or technological properties were not significantly impaired (Report, 1981, p. 12).

The Codex Alimentarius Commission has also written a Recommended International Code of Practice for the Operation of Radiation Facilities Used for the Treatment of Foods (Codex, 1984b). This document lists general principles relating to shielding, dosimetry and process control, and inventory control. The code of practice is furnished as guidance for irradiation operators and governmental regulators; it does not circulate for approval by the member countries.

International Opportunities for Training and Research

The International Facility for Food Irradiation Technology (IFFIT), was jointly established by the FAO, the IAEA, and the Dutch Ministry of Agriculture and Fisheries in 1978. Its purpose is to serve as an international training project and accelerate the commercialization of food irradiation in developing countries. The IFFIT uses the Dutch Pilot Plant for Food Irradiation to train prospective users of this technology and to irradiate sample foods as part of feasibility studies. As of November 1985, 190 scientists and officials from 45 countries had participated in the eight IFFIT training courses (Farkas, 1985, p. 3, updated by author). In addition to training manuals, the IFFIT also publishes scientific research reports on various aspects of food irradiation.

On May 9, 1984, an International Consultative Group on Food Irradiation was established to provide continued international cooperation in the food irradiation area. This consultative group will operate for an initial period of five years, and currently there are 20 member countries, including the United States. [1] The major duties of the group will be to evaluate global developments in the field of food irradiation; provide advice on the application of this technology; and furnish requested information to the Joint Expert Committee on the Wholesomeness of Irradiated Food and the Codex Alimentarius Commission.

[1] The 19 other member countries, as of April 1985, are Argentina, Australia, Bangladesh, Canada, Egypt, the Federal Republic of Germany, France, Hungary, India, Iraq, Israel, Italy, Malaysia, Mexico, the Netherlands, the Philippines, Syria, Turkey, and Yugoslavia (Anon., 1985, p. 5-7).

These two international groups supplement the activities of the Joint FAO/IAEA Division of Isotope and Radiation Applications of Atomic Energy for Food and Agricultural Development, headquartered in Vienna, Austria, which organizes symposia, supports coordinated research programs, and publishes the quarterly Food Irradiation Newsletter. Interest in food irradiation outside the United States is great as witnessed by the 21 international meetings on the the subject held during 1981-1983 (Farkas, 1984, p. 4-8). Numerous other meetings focusing on food irradiation were held in individual countries.

Commercial Experiences

As of August 1985, 27 countries had issued unconditional and provisional clearances allowing irradiation to be used commercially on a variety of foods (table IX-1). However, less than ten countries are actually using the process commercially, and the quantities involved are very small. It is estimated that the world's total production of irradiated foods amounted to 35,000 tons in 1983 (van Kooji, 1984). 3/ In many cases, irradiators primarily intended for sterilizing disposable medical supplies are used on a part-time basis to irradiate food items and conduct food-related research. Consumer reaction to irradiated foods in some of these countries is discussed in the chapter on benefits and consumer acceptance.

Japan

The Japanese have operated a commercial plant since 1973 that has irradiated an average of 15,000 tons of potatoes per year (Farkas, 1984, p. 20). In recent years, the Shihoro Potato Irradiator has operated closer to its monthly capacity of 10,000 tons for the three month period when it is used (Umeda, 1983, p. 24). The Shihoro Potato Irradiator was built as part of a warehouse and processing complex operated by the Shihoro Agricultural Cooperative in Hokkaido for an approximate cost of 1.3 million U.S. dollars (ibid, p. 26). Japanese food additive laws do not allow use of the chemicals applied in the United States to keep potatoes from sprouting during storage (ibid, p. 19).

The main objective of the irradiation treatment is to stabilize the supply and market price of potatoes during the three month off season (Umeda, 1983, p. 20). In addition, the irradiator has been successful in filling in production gaps with good quality potatoes, allowing processing plants to operate eleven months of the year (ibid, p. 28). Only about 20 percent of the irradiated potatoes are sent to the consumer market (ibid, p. 27). Irradiated potatoes in 22 and 44 pound packages are labeled "Product treated by irradiation," and re-irradiation of potatoes or potato products is prohibited (Kawabata, 1981, p. 447). Despite the apparent success of the Shihoro Potato Irradiator, the Japanese government has not approved the use of radiation on any other foods.

3/ This 35,000 tons does not include the amount of grain treated with radiation in the Soviet Union discussed later in this section.

Table IX-1. International Clearances for Food Irradiation--August 1985 1/

Country	Food Product
Argentina	Potatoes
Australia	Frozen shrimp
Bangladesh	Potatoes, onions, wheat and wheat flour, spices, chicken, fish, frozen shrimp, frozen frogs' legs, rice and rice products, pulses, papayas, mangoes
Belgium	Potatoes, onions, garlic, shallots, spices, strawberries, gum arabic, dried vegetables
Brazil	Potatoes, onions, rice, beans, maize, wheat and wheat flour, spices, papaya, strawberries, fish and fish products, poultry
Canada	Potatoes, onions, wheat and wheat flour, spices
Chile	Potatoes, onions, wheat and flour, spices, rice, chicken, fish and fish products, cocoa beans, dates, pulses, papayas, mangoes, strawberries
China	Potatoes, onions, garlic, peanuts, grain, mushrooms, sausage
Denmark	Potatoes
France	Potatoes, onions, garlic, shallots, spices, dried vegetables, mechanically deboned poultry meat
German Democratic Republic	Onions, spices, and enzymes
Hungary	Onions
Israel	Potatoes, onions, poultry, garlic, shallots, spices
Italy	Potatoes, onions, garlic
Japan	Potatoes
Netherlands	Potatoes, onions, spices, mushrooms, chicken, frozen fish, frozen and boiled shrimp, frozen frogs' legs, rice and rice products, rye bread, dried vegetables, egg powder, malt, blood proteins
New Zealand	Herbs and spices
Norway	Spices
Philippines	Potatoes, onions, garlic
Poland	Potatoes, onions
South Africa	Potatoes, onions, garlic, chicken, papayas, mangoes, strawberries, pickled mango, bananas, litchis, avocadoes, fruit juices (frozen), green beans, tomatoes, brinjals, soya pickle products, ginger, vegetable paste, dried bananas, almonds, cheese powder, yeast powder, herbal tea, spices, dried vegetables
Spain	Potatoes, onions
Thailand	Onions
United States	Potatoes, wheat and wheat flour, spices, dried enzyme preparations, fresh pork
Uruguay	Potatoes
USSR	Potatoes, onions, dry food concentrates, grain, dried fruits
Yugoslavia	Potatoes, cereals, legumes, onions, garlic, dried fruits and vegetables, egg powder, tea extracts, herbal tea, fresh poultry

1/ This lists includes unconditional and provisional clearances for commercial sale, but not clearances for experimental or test marketing trials.
Source: Anon. (1985b).

Netherlands

The Netherlands has been very active in the food irradiation field in the last several years. Besides providing a pilot plant irradiator for the IFFIT, the Dutch have a multipurpose service irradiator located in Ede that irradiates about 70–85 tons of food a week. The main food products are spices, marine products, egg powders, and dried vegetables which are treated for microbial control purposes. Fresh agricultural products are not generally treated (Leemhorst, 1984, p. 2). Packages of irradiated foods sold in the Netherlands must carry the symbol shown in figure 1, but no descriptive term is required (Oosterheert, 1984, p. 40).

Figure 1.

South Africa

Irradiated foods were first introduced to the South African market during 1978–79 marketing trials of irradiated potatoes, mangoes, papayas, and strawberries. Currently, there are three irradiators in South Africa that treat food. The newest plant, upgraded by HEPRO, Inc. in 1981, is devoted solely to irradiating food. In 1984, 8,000 tons (converted to 100 krad [1 kGy] equivalent) of fresh fruits, some vegetables, and mango achar (pickled mango) were irradiated for distant South African markets. An older radiation processing company that uses gamma radiation to sterilize disposable medical products and crosslink plastics, irradiated about 18,000 tons of dry and dehydrated foods and spices in 1984. A government-owned irradiator was converted into a commercial plant in 1984, and its output of food for the year was about 2,000 tons (Du Plessis, 1984). A variety of foods—meats, spices, potatoes, onions, and asparagus—have been treated, but the dominant food product has been strawberries. Recent items include herbal tea, sugar cane yeast, pickled mango, and vegetable pastes (van der Linde and Brodrick, 1985, p. 3). No labeling is required for irradiated foods sold in South Africa (de Wet, 1985, p. 5).

Soviet Union

Semi-commercial scale disinfestation of grain has been reported at the Odessa port elevator in the Soviet Union (Zakladnoi et. al., 1982, p. 76). The irradiation facility, which consists of two 1.4 MeV with 20 kw beam power electron accelerators, was placed in service in 1980 (ibid, p. 76–77). Each accelerator is capable of irradiating 200 tons of grain per hour. Through January 1983, 250,000 tons of grain have been disinfested by irradiation at this facility (van Kooij, 1985).

Belgium

The Belgium "Institut Nationale des Radioelements" has a small food irradiation program. In 1984, about 3,000 tons of dried vegetable ingredients, frozen products, spices, food for laboratory animals, and enzymes were irradiated (Etienne and Buyle, 1984, p. 6).

Spices and dry vegetable seasonings are irradiated in Norway, France, and the United States (Farkas, 1985, p. 9). An Italian vegetable irradiator is under construction and scheduled to be operational in autumn 1985 (van Kooij, 1985).

Other activities

Experiments on appropriate uses of low and medium doses of radiation to reduce food loss and improve hygenic quality have been conducted around the world since the 1950's. For many countries, this experimentation has evolved to the stage of pilot scale trials and market testing of various irradiated foods and animal feeds. For a fuller discussion of these activities, the reader is referred to J. Farkas' excellent review of recent international activities in food irradiation (Farkas, 1984). Another source of information is the proceedings from the FAO/IAEA International Symposium on Food Irradiation Processing held in Washington, D. C., March 4-8, 1985. Participants from 22 countries presented papers on technical and economic feasibility studies, recent regulatory activities, and prospective national food irradiation centers.

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X. MAJOR FEDERAL RESEARCH AND DEVELOPMENT ACTIVITIES

Federal involvement in food irradiation research dates from the "Atoms for Peace" program established by President Eisenhower in the early 1950's. From 1953 to 1960, the Army Quartermaster Corps was responsible for research on both low- and high-dose food irradiation applications. In 1960, the Atomic Energy Commission (AEC), the predecessor agency of the Department of Energy, was given responsibility for research on radiation's food applications below 1,000 krads (10 kGy). During the 1960's, AEC funded dozens of government and university research projects on the potential use of low and middle dose radiation in extending the shelf lives of fresh commodities. AEC built several cobalt-60 research and pilot irradiators for conducting technical and economic feasibility studies (see Dietz, 1965).

Army's Research at Natick

After 1960, the Army concentrated its research efforts on developing radiation-sterilized meat products to substitute for canned or frozen military rations. During 1961-1962, AEC constructed a large food irradiation laboratory at the U.S. Army Natick Laboratories in Natick, Massachusetts. The Natick facility had two radioisotope sources--cobalt-60 and cesium-137--and an electron linear accelerator (Josephson, 1983, p. 168). In addition, the facility included a fully-equipped food preparation area to allow flexibility and complete control over all aspects of food experiments. Supporting chemistry, packaging, and microbiology laboratories were added to complement the irradiation facility. Many years of experiments were conducted on radiation-sterilized meats to determine the most appropriate dose, optimal atmosphere and temperature conditions during irradiation, necessary pre and post treatment of the meats, and compatible packaging materials.

The Natick facility also prepared the irradiated meats for the animal feeding studies begun in 1971 and 1975 to determine the wholesomeness of radiation-sterilized beef, pork, ham, and chicken (Josephson, 1983, p. 170-171). The Army estimated that it would submit petitions to the Food and Drug Administration for approval of irradiated beef in 1977 and irradiated ham, pork, and chicken in 1981 (GAO, 1978, p. 7). However, in 1977 the Army declared the private contractor conducting the beef, pork, and ham studies in default for deficiencies in conducting the animal feeding studies (ibid). The sterilized chicken studies were conducted by another firm and continued. A 1978 General Accounting Office (GAO) report recommended that the Army develop a plan to complete the food irradiation program by restricting animal feeding studies to those needed to obtain approval of irradiated chicken. GAO also recommended that the Army evaluate the need for continuing food irradiation research by Natick at the $3-million-a-year level and determine the desirability of further Government investment in high-dose sterilization of meats (ibid, p. 41).

In 1980, responsibility for food irradiation research, including the wholesomeness assessment of radiation-sterilized chicken, was transferred from the Army's Natick laboratories to USDA's Eastern Regional Research Center in Philadelphia. The Natick irradiation facility was subsequently closed, and the isotopes were moved to USDA's Philadelphia research center and the University of Lowell in Massachusetts.

Department of Energy (DOE)

DOE's current interest in food irradiation falls under the Byproducts Utilization Program established in 1977 to find uses for the nuclear wastes from weapons production. The focus of DOE's food irradiation activities is on low dose radiation treatment of foods at levels below 100 krads (1 kGy), especially insect disinfestation of fresh produce and inactivation of parasites in meat (Gilbert, 1984, p. 3). The radiation source for these applications is cesium-137, a radioactive material separated from defense nuclear waste material.

DOE has funded several food irradiation research contracts in conjunction with the U.S. Department of Agriculture (USDA) and several universities. The purpose of these reseach efforts is to determine the radiation dose that achieves the intended purpose, but does not adversely affect the exposed commodity. Applications under study include: disinfesting Florida grapefruit and California almonds, raisins, and walnuts; cleansing clams and other shellfish harvested from polluted beds along the eastern coast of the United States; and inactivating trichinae parasites in ground and fresh pork. To supplement this pork irradiation research, a recent study contracted by DOE looked at the economic feasability of irradiating pork carcasses to control trichinae parasites (CH2M Hill Central, Inc., 1983). In another study funded by DOE and the National Pork Producers' Council, a national sample of consumers were interviewed to learn their reaction to the irradiation concept and a series of descriptive terms for the process. Some findings of this study are discussed in the chapter on benefits and consumer acceptance.

To more closely simulate commercial conditions, DOE is funding a $1 million truck-mounted irradiator to conduct experiments close to production areas. The irradiator was built by Foster Wheeler, and the shipping cask, which will contain 250,000 curies of cesium-137, was built by Nuclear Packaging Co. The irradiator and shipping cask are awaiting safety reviews and final approvals. DOE's transportable cesium irradiator was scheduled to be available for experiments under the supervision of USDA's Agricultural Research Service in 1985. The first commodities planned for testing are apples, cherries, and nuts in the Pacific Northwest.

Similar experiments were conducted in the 1960's using a truck-mounted cobalt-60 irradiator built and owned by the Atomic Energy of Canada, Limited. This irradiator contained 40,000 curies of cobalt-60 and was used in a set of experiments on the possibilities of extending the shelf life of fresh fruits and vegetables. The results of these experiments were reported in two USDA publications (Bramlage and Lipton, 1965, and Bramlage and Couey, 1965). The irradiator was returned to Canada and subsequently dismantled.

DOE Demonstration Facilities

DOE is sponsoring two projects designed to demonstrate the commercial feasibility of cesium-137 irradiation. DOE has contracted with Rockwell International to build an irradiator that will treat between 1,000 and 4,000 cartons of produce per 8-hour shift for fruit fly contamination and shelf life extension. The irradiator will contain 3 million curies of cesium-137. DOE is negotiating a cooperative agreement with the National Food Processors Association to locate the $3 million facility at their newly purchased research

and development laboratory in Dublin, California. Building the irradiator at that site is also subject to city approval. The facility is to be used as a research and training facility for interested people from Government, industry, and the international community.

DOE also has plans for a research and demonstration facility for low-dose irradiation of fresh meat to rid it of health threatening microorganisms. The irradiator will contain about 2.5 million curies of cesium-137 and will be capable of treating several hundred carcasses or boxed products per day. DOE wants to locate the irradiator in a university setting adjacent to a meat processing facility with Federal inspection services available.

Research Activities of USDA

The Agricultural Research Service (ARS) of USDA has conducted studies on irradiation's technical effects on food for over 20 years (Bramlage and Couey, 1965; Bramlage and Lipton, 1965). ARS has several active programs investigating the efficacy of irradiation disinfestation of fruit, as well as any phytotoxic drawbacks. One of the objectives is to determine if irradiation can technically substitute for chemical fumigants used to disinfest fresh produce for quarantine purposes. Research on irradiation of Hawaiian papaya is sufficient for USDA's Animal and Plant Health Inspection Service to prescribe a quarantive treatment level (Secretary of Agriculture, 1985). Research on irradiation of citrus fruit and mangoes for fruit fly control is a couple of years from completion. ARS scientists in Washington and California are also studying its efficacy and phytotoxicity for codling moth disinfestation of apples, dried fruit, and nuts.

Research at ARS' Savannah, Georgia laboratory has focused on irradiation's suitability for killing moths and beetles that infest stored grains. This work led to FDA approval of irradiation disinfestation of wheat and wheat flour in 1963. A pilot-scale irradiator, designed to irradiate both bulk wheat and packaged products, was built at the Savannah laboratory in the mid-1960's by AEC to explore the commercial feasibility of irradiating grain (Dietz, 1965, p. 307-8).

ARS' Eastern Regional Research Center

ARS also conducts food irradiation research at the Food Safety Laboratory of ARS' Eastern Regional Research Center (ERRC) (Thayer, 1984). An early project at this laboratory was a study of the efficacy of irradiation in replacing or reducing the nitrite used for preserving bacon. In 1980, responsibility for the wholesomeness studies of irradiation-sterilized chicken products was transferred from the Army's Natick laboratories to this group. The data from these studies on high dose irradiation were submitted to the Food and Drug Administration in March 1984. The data are also available to the public through the National Technical Information Service.

Current work at the ERRC concerns the importance of sugar on the microbial safety of irradiated bacon processed with reduced nitrite. Researchers are studying shelf life, quality, radiolytic products, and sucrose and nitrosamine concentrations. Bacon samples have been irradiated with either electrons or gamma rays at doses between 750 and 3,000 krads (7.5 to 30 kGy) at 5oC (41oF). In another study, scientists are examining the effects of

low and medium dose irradiation (up to 1,000 krads (10 kGy)) on the decomposition of fresh chicken and beef muscle during extended storage. Food Safety Laboratory scientists are also studying irradiated polyunsaturated lipids, their peroxide formation, and decomposition products. The newest project at the ERRC involves lower doses of gamma radiation on meats and poultry to extend shelf life, reduce microbiological spoilage, and reduce or eliminate food poisoning bacteria, such as salmonellae, while maintaining acceptable quality.

In addition to the above studies, researchers in the Plant Science Laboratory are studying the biochemical and physiological reasons for softening and other effects in irradiated blueberries, tomatoes, and other fruits. This laboratory also plans to look into ways to alleviate radiation's negative effects on fresh produce through the use of low energy, surface treatment and through combining the radiation exposure with other treatments, such as controlled atmosphere storage and use of chemical fungicides.

Earlier Economic Analyses

On two occasions, agricultural economists with the Economic Research Service and other USDA agencies analyzed the economic feasibility of irradiating selected products (Droge, 1965, and Bird, 1972). The 1972 cost-benefit analysis recognized six commodities--strawberries, mushrooms, papayas and mangoes, East Coast finfish, shrimp, and blue crabs--out of a list of 61 foods as being the most promising candidates for low and medium dose radiation treatment.

Department of Commerce Activities

The Commerce Department has also had an interest in food irradiation over the years. In the late 1960's, the Commerce Department's Business and Defense Services Administration published several status reports on food irradiation, including a list of firms offering irradiation services or design and engineering expertise (Food Irradiation, 1968). In 1972, another Commerce agency conducted an analysis on the costs and benefits to the Armed services of replacing thermally-sterilized meat rations with shelf stable irradiated meats. The researchers concluded "the cost of processing and distributing food to U.S. troops in South Vietnam could have been reduced by approximately $18 million in fiscal year 1968 if five irradiation sterilized ration items (meats) had been available to replace just their frozen and chilled counterparts" (Deitch, et. al., 1972, p. 3).

The Commerce Department was the lead agency in the Interdepartment Committee on Radiation Preservation of Food during its existence from 1956 until about 1980. This Committee served as a focal point for federal research activities on food irradiation. In 1983, Philip Lewis prepared a report on current food irradiation activities and changes in U.S. regulations (Lewis, 1983). Lewis is also the chairman of an interagency task force on food irradiation. The task force, composed of researchers and regulators working in this area, meets quarterly to exchange information on their respective activities and interests.

National Marine Fisheries Service

The National Marine Fisheries Service (NMFS), a research and statistical reporting agency within Commerce, conducted many years of experiments on ionizing radiation's ability to extend the shelf life of a variety of fresh fish and shellfish.1/ Researchers also looked at other aspects of the commercial feasibility of this treatment. In 1964, a semi-commercial scale irradiator containing 235,000 curies of cobalt-60 was built by the Atomic Energy Commission at the NMFS research facility in Gloucester, Massachusetts (Naylor, et. al., 1985). The facility was designed to irradiate 2,000 pounds of fish an hour at a dose of 200 krads (2 kGy). The Gloucester irradiator has never received any additional cobalt-60, so the source's activity is very low. At the time the authors visited the facility, the irradiator was being used to sterilize food for laboratory animals for a dental experiment in progress at a nearby university. Researchers at the Gloucester research center also conducted studies of the feasibility of irradiating fish at sea with a shipboard irradiator. The scientists found that irradiation at sea requires about a third of the dose needed when fish are irradiated after landing (Carver, et. al., 1968, p. 11).

Currently, the NMFS is partially funding a market research study to understand consumers' attitudes toward food irradiation and to develop effective education strategies and techniques. The NMFS has contracted with Brand Group, Inc., a Chicago-based consulting firm, to collect and analyze consumers' responses to irradiation technology and evaluate alternative education approaches (Brand Group, Inc., 1984). The study will include a detailed analysis of the comments received by the Food and Drug Administration in response to their proposed rule extending the use of radiation on foods. The $150,000 project, of which the NMFS is contributing half the cost, will be concluded by the end of 1985.

National Bureau of Standards

The National Bureau of Standards' (NBS) involvement in food irradiation is at a more basic inputs research level. NBS has supplied expertise and calibration standards to U.S. irradiation companies in the area of dosimetry--the measurement of radiation doses (McLaughlin et. al., 1983). Dosimetry is the most expedient and accurate means of quality control in radiation processing. Scientists at NBS have developed and tested inexpensive practical dosimetry systems which are marketed commercially. NBS scientists also serve on task forces that develop voluntary industry standards and protocols for radiation measurement assurance in food irradiation applications.

In addition to dosimetry research, NBS conducts research on the chemical interaction of radiation and foods (Simic, 1983; Simic et. al., 1983). Scientists have found that some of the chemical substances formed when amino acids are irradiated are unique to radiation processing. Researchers are hopeful that these unique radiolytic products can be used as a post-irradiation technique to determine whether a food has been irradiated and, possibly, the radiation dose it absorbed.

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The large volume of product needed to achieve low average treatment costs dictates a geographically restricted approach. Thus, irradiation is more likely to be used in industries where there is a consolidating point early in the marketing chain. In this way, additional transportation to the irradiation facility is not incurred. Seasonal products would naturally have attractive because of periods of the crop passing through handlers to market, along with large volumes, another desirable characteristic is shown, year round production-a quality not inherent to most fruits and vegetables. Meat and poultry slaughter, however, have more exacts and controllable production cycles.

Toward Our Benefits

Irradiation's use on foods partially depends on the future of current alternative treatments. The major reason for the rapid growth of radiation sterilization of medical supplies is the stricter standards imposed by the Occupational Safety and Health Administration for worker exposure to the commonly-used ethylene oxide gas. As more chemicals share the fate of ethylene dibromide (EDB), irradiation's future as a disinfestation treatment brightens. For uses where disinfestation is not important, such as satisfying a quarantine requirement prior to export, irradiation may be appropriate.

Another potential benefit of irradiation is to lessen the incidence of foodborne diseases, such as salmonellosis and trichinosis. This use will depend on either the desire of the food industry to improve consumer acceptance of a product by lessening the potential for disease or the government's decision to impose stricter standards for microbiological safety.

Radurization-sterilized meats in airtight cans or plastic pouches are likely to have a limited market in the United States because of established consumer preferences for traditional fresh and processed meats and high production costs. Canned meats are not a high volume item in U.S. supermarkets. Irradiation costs are likely to be high because of the large dose, supplementary treatments needed to preserve quality, and protective packaging required. Radurization-sterilized meats were developed by the Army as a possible replacement for traditional canned rations and may be demanded for specialty uses-submarines, space shuttles, camping trips, and other uses where space and weight are important considerations.

Consumer and Processor Acceptance

U.S. consumers' willingness to purchase irradiated foods is an important, and unknown, consideration. Consumer acceptance of irradiation in other countries has been mixed. Irradiated potatoes in Japan met with opposition by consumer groups. In South Africa, where irradiated food is not labeled at the retail level and the initial test marketing was accompanied by an intensive educational campaign, irradiated strawberries, herbal teas, and dried fruits are successfully sold. U.S. food processors say that the results of an educational campaign targeted toward their product. Companies do not want to risk the good will of their brand names if irradiated foods are to received by consumers. On the same time, there could be benefits from being the first to market "safer" food products such as trichinae-safe pork or salmonellae-free chicken.

Policy Issues and Questions

Every technology involves risks and benefits. Chemical treatment of food places consumers, workers that handle the chemicals, and the environment at varying degrees of risk. Irradiation's use of radioactive materials or machine-produced radiation introduces additional concerns over its desirability and greater public responsibility for its safe use. The following questions highlight some of the public policy issues raised in the food irradiation debate.

Is further testing of the safety of irradiated foods needed? Should the Government sponsor this research?

While the Codex Alimentarius Commission has accepted the safety and wholesomeness of foods irradiated up to an overall average dose of 1,000 krads (10 kGy), critics of food irradiation maintain that uncertainties about safety remain (Tauber and Alvarez, 1984). They point to studies that suggest irradiation stimulates aflatoxin production in grain and eating irradiated food may lead to immune system problems. 2/ Critics of food irradiation are also concerned about the possibility of creating radiation-resistant bacteria and viruses. They question some of the findings from a series of Government-funded animal feeding tests performed with irradiation-sterilized chicken. They are concerned about the creation of free radicals in irradiated foods and the hypothesized link between free radicals and cancer and other degenerative diseases (Ames, 1983, p. 1260-1). Critics are calling for additional safety tests to look at these and other issues. They do not feel that long-term safety in humans has been proven.

Another area of regulatory concern is that safety tests for irradiated foods be conducted under conditions likely to be used in a commercial setting. Atmospheric conditions, temperature, pre and post treatment of the product, and other factors influence radiation's effects on food. For example, if a food product generally receives a pesticide or fungicide treatment or a chlorine solution wash, it is important that experimental work on irradiation of this product replicate these conditions. Undesirable interactions between the pesticide or chlorine and the radiation could require a modification in current practices if irradiation is to be used.

Some scientists advocate establishing an irradiated food's safety through radiolytic/dosimetry studies, rather than animal feeding studies. These chemical examinations would try to determine the effects of radiation on the food's

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2/ Aflatoxins are naturally occurring poisons caused by molds found in certain foods, particularly nuts, grains, and seeds. Aflatoxins have been shown to cause liver cancer in laboratory animals and may be linked to cancers of the stomach, liver, and kidney in humans (National Institutes of Health, 1986, p. 181).

Possible immune system complications have been suggested by dose-related increases in polyploid white blood cells in malnourished children in India fed freshly irradiated wheat, by kidney research with rats in Russia fed an irradiated lab diet, and by DNA metabolism changes in spleen cells of Chinese hamsters fed irradiated fish in Germany (Chikankin, 1978; Shankaran and Sankaran, 1975; Levina and Ivanov, 1978; Renner, et. al., 1982).

chemical constituents and whether any toxic compounds are produced. Industry is generally reluctant to devote resources to such basic scientific research. This type of research could also lead to a reliable method for determining if food has been irradiated.

Would workers in commercial food irradiators be at high risk?

Facilities using radioisotopes must satisfy the radiation safety requirements of the U.S. Nuclear Regulatory Commission (NRC) or a set of similar requirements enforced by the 27 agreement States. Users of machine-produced ionizing radiation must satisfy State regulations (chapter VIII). The NRC and State regulations, covering irradiator design and operating procedures, are designed to protect both workers in the facility and the general public.

Radioisotopes have been used for commercial irradiation for about 20 years. Richard Cunningham, Director of NRC's Division of Fuel Cycle and Material Safety, reported that in 1984, there were 35 commercial gamma irradiators licensed by the NRC or the 27 agreement States (Cunningham, 1984, p. 2). Two major radiation exposures have occurred when workers failed to follow the proper operating procedures (ibid, p. 3). NRC's regulations were subsequently amended to require automatic systems designed to ensure that a worker cannot enter the irradiation cell when the radioactive source is unshielded (ibid). Similar requirements exist for machine-produced radiation to prevent workers from walking into the cell when the machine is on.

Can the dose applied to a food be determined?

One of the major regulatory problems with food irradiation is that there is no commercially available method to determine if a food has been irradiated and at what dose. Foods treated with chemical preservatives can be tested to see whether too much or too little of the preservative was added. However, the only readily discernable difference between irradiated and non-irradiated foods may be the cleanliness of the irradiated product. Chemical changes induced by radiation also dissipate over time.

Research has been conducted in Germany and Japan to develop testing methods for irradiated foods. Recently, scientists at the Institute for Radiation Hygiene in the Federal Republic of Germany have developed a chemiluminescence method to identify some irradiated foods (Bogl and Heide, 1983, p. 2). They report that the technique will only work on dry foods, such as spices and milk powder, and that the chemiluminescence intensity of different foods irradiated at equal dose levels may vary considerably (ibid). In 1980, the Japanese reported initial findings from experiments using ultraviolet light to identify fish irradiated at doses of 300 krads (3 kGy) (Kawabata, 1981, p. 397). Until a post-irradiation testing method is developed, regulating food irradiation must be based on processing records, not analysis of the product.

Should irradiated foods be labeled at the wholesale, retail, and/or restaurant level?

The issue of labeling irradiated food ingredients and products has important implications for both processors and consumers. There is general agreement that wholesale items should be labeled to alert purchasers that the ingredient or food has already been irradiated. Otherwise product

characteristics could be altered by re-irradiating and inadvertently getting too much exposure to radiation. Less agreement exits about retail labeling of irradiated foods. Chapter III discusses some of the retail labeling issues and how three foreign countries deal with them. Consumer groups in the United States want irradiated foods labeled at the retail level to allow consumers to chose whether they want to purchase irradiated food. They argue that retail labeling would also assist in a recall effort if one became necessary. Another reason for labeling irradiated foods is to alert purchasers about any special storage or preparation requirements.

Should the Government inform consumers about food irradiation?

Consumer acceptance of irradiated foods and willingness to purchase them are critical to the commercial success or failure of food irradiation. Consumers who are unfamiliar with the technology may erroneously conclude that irradiated food is radioactive and could lead to radiation poisoning. At a 1985 international symposium on food irradiation, consumer acceptance was recognized as an essential prerequisite to introducing the process (Anon., 1985a, p. 18). The summary panel went on to say "all available methods of achieving this objective should be exploited; the production of both written and audio-visual material by international agencies, governments, and representatives of industry should be encouraged" (ibid).

Governments of several countries, including South Africa, the Netherlands, Israel, and Hungary, have conducted market tests of various irradiated foods. In South Africa, the tests were accompanied by an educational campaign. The South African government also sponsored a two-day national symposium to present the results of the market tests and discuss future prospects. A National Steering Committee for Radurised Food was set up to coordinate all aspects relating to the marketing of irradiated food. The Committee is composed of representatives from the Department of Agriculture and Fisheries, the Atomic Energy Board, the radiation and food industries, and the Consumer Council (Webb, 1983, p. 83).

The role of the U.S. Government in consumer education has not been decided. A few articles discussing food irradiation have appeared in consumer-directed Government publications; but there has been no widespread effort to provide educational materials for either food companies or consumers. Some observers argue that it is up to the food industry to inform consumers, citing the introduction of microwave ovens, which was not accompanied by a Government information campaign. Others argue that the food industry knows the most effective way to reach consumers. However, on such a sensitive topic consumers may be more receptive to materials from the Government and industry may welcome Government involvement.

Can the training needs of operators and regulators be met?

Much of the necessary radiation physics knowledge could be gained via classroom instruction. However, some practical, on site instruction will also be required.

The Government has very few large irradiators. Most of USDA's irradiators are small facilities used to sterilize insect pests for depopulation programs. The Army's food irradiation facility in Natick, Massachusetts had

two radioisotope sources--cobalt-60 and cesium-137--and an electron linear accelerator. This facility was closed after responsibility for food irradiation research was transferred to USDA in 1980. The National Marine Fisheries Service's irradiator in Gloucester, Massachusetts is still operative, but the cobalt-60 has very low energy 20 years after being installed.

The International Facility for Food Irradiation Technology uses the Dutch Pilot Plant for Food Irradiation in Wageningen, the Netherlands to provide "hands-on" training in irradiator operation. Historically the pilot plant has been reserved for use by scientists and technicians in the Netherlands and developing countries.

Commercial-scale facilities like the Department of Energy's (DOE) agricultural commodities irradiator (chapter X) will provide training opportunities for operators and Federal and State inspectors. However DOE's irradiator is planned to contain cesium-137, not cobalt-60 or a machine source. Commercial irradiation facilities are also possible training sites if the facilities' owners agree to make their plants available. Firms that buy irradiation equipment are generally able to receive on-site training from the seller.

Should the Government start producing cobalt-60 or can we continue to rely on private and foreign supplies?

Cobalt-60 is in many respects the most desirable radiation source for treating food. It is produced by placing non-radioactive cobalt-59 in a nuclear reactor for one to one and half years. In the reactor, each cobalt-59 atom absorbs a neutron that transforms it into radioactive cobalt-60. In the Western Hemisphere there are only three commercial suppliers of cobalt-60: the Atomic Energy of Canada Ltd. (AECL) in Ottawa, Canada; Neutron Products, Inc. in Dickerson, Maryland; and General Electric Nuclear Energy Division in Pleasanton, California (Jarrett, 1982, p. 139).

AECL, a Canadian crown corporation, supplies over 80 percent of the world's cobalt-60. 3/ In 1984, the United States imported 12.4 million curies of cobalt-60 from Canada valued at $11.5 million (U.S. Bureau of the Census, 1984). Because of the temporary closing of two of four Canadian reactors producing cobalt-60 in 1982, AECL has not had enough cobalt-60 to meet demand for the last few years. However, AECL has contracted with an additional 11 reactors for future supplies of cobalt-60. At an international meeting on food irradiation held in March 1985, an official of AECL told the group that AECL planned to have 16 million curies of cobalt-60 available in 1985, 25 million curies in 1986, 35 million curies in 1987, and 50 million curies in 1988. 4/

3/ A crown corporation is a semi-autonomous government organization used to administer and manage public services. In crown corporations, business enterprise and public accountability are combined.

4/ An irradiator designed to disinfest 50 million pounds of fresh produce a year with a 26 krad (.26 kGy) dose would need about 100,000 curies. An irradiator applying a higher dose of 250 krads (2.5 kGy) to 100 million pounds of chicken would need about 2 million curies. These calculations are based on a 21-hour processing day, five days per week and assumes a steady year-round processing rate. Both calculations also assume a 25 percent net utilization efficiency of cobalt-60. An irradiator designed to increase the net utilization efficiency would require less cobalt.

Cobalt-59 could also be placed in U.S. nuclear power plants and be converted into cobalt-60. However, the design of the Canadian reactors is more suitable for this conversion than American reactors. Transformation of cobalt-59 in U.S. commercial reactors is at the expense of more valuable power production. Also, U.S. power plants are very hesitant to introduce any changes in operating procedures once they have their plants licensed and running. Annual production of cobalt-60 by the two American companies is small--less than 2 million curies.

During the 1960's, DOE produced cobalt-60 for sale to commerical users and for use in Government funded experiments. However, as commercial suppliers of this isotope emerged, DOE withdrew from major production of cobalt-60 by 1968 (Maddox, 1985). Currently, DOE produces approximately 700,000 curies per year in the Advanced Test Reactor in Idaho (Gilbert, 1984, p. 16). DOE recently announced its plans to produce 3 million curies of cobalt-60 per year by 1991 at its Fast Flux Test Reactor in Hanford, Washington (CRA Info, 1985, p. 1). DOE's heavy-water reactors at Savannah River in South Carolina could produce large amounts of cobalt-60. However, current defense commitments preclude cobalt-60 production until the 1990's (Gilbert, 1984, p. 16).

The price of cobalt-60 is largely dependent on reactor fuel charges associated with its production. In 1968, the price of radiation processing grade cobalt-60 in lots of 100,000 to 1 million curies ranged from 30 to 40 cents per curie, depending on technical specifications and order terms, especially lead time (Deitch, et. al., 1972, p. 64). Cobalt-60 from AECL delivered prior to July 1, 1985, sold for between 95 and 102 cents per curie, depending on volume purchased (Bloomster et. al., 1985, p. 15). AECL has indicated that they expect cobalt-60 prices to rise by 7.5 percent or less a year compared with the 10-percent annual price increases of recent years (Fraser, 1986). DOE is projecting to sell their 3 million curies for about $1.10 per curie (CRA Info., 1985, p. 4).

Another possible source of gamma radiation is radioactive cesium-137. Cesium-137 is obtained by running a nuclear reactor's spent fuel through a multi-million dollar fuel reprocessing facility. There were plans to build three commercial reprocessing facilities by 1985 (Jarrett, 1982, p. 146). However, these plans were cancelled by President Carter's 1977 decision that the United States would not engage in commercial reprocessing of spent nuclear fuel.

Extracting the cesium-137 from nuclear waste has the potential to ease waste management by removing a source of heat and penetrating radiation. DOE has extracted and encapsulated 77 million curies of cesium-137 from defense reactor waste (Gilbert, 1984, p. 15). 5/ These 77 million curies have already been committed at a lease price of 10 cents per curie to various

5/ Although cesium-137 has a longer half life than cobalt-60--30.3 years compared to 5.26 years--the gamma rays from cesium-137 are less penetrating and more self-absorption occurs. Also, DOE's cesium-137 is in the form of WESF capsules designed for storage, not industry use. The capsules have high self-absorption, and it would take about seven times more DOE cesium than AECL cobalt to process an equal amount of products (McMullen and Sloan, 1983, p. 6).

DOE projects and commercial U.S. irradiators (ibid; McMullin and Sloan, 1983, p. 9). Obtaining more cesium-137 would involve reprocessing other defense reactor wastes and spent fuel from commercial power plants. The monetary costs of reprocessing and the desirability of the uranium and plutonium produced during the reprocessing must be weighed against the waste management assistance and the need for additional cesium-137.

Would food irradiation add to the transportation of radioactive material?

Widespread use of gamma irradiation for foods will increase the transportation of radioisotopes somewhat. During a years' time, about 12.5 percent of cobalt-60 and 1 percent of cesium-137 decays. The decayed portion of the radioisotopes must be replenished to maintain the amount of product able to be treated. Cobalt-60 irradiators with large loadings may receive replenishments every year or two, while irradiators treating small quantities or administering lower doses are likely to purchase extra cobalt initially, rather than incur the transportation and loading costs each year.

Getting the radioisotopes from the reactors to the encapsulation sites and then to the final user requires that the isotopes be shipped across highways. Special shipping casks for radioactive material have been tested and approved by the U.S. Department of Transportation (DOT). However, some communities prohibit transport of nuclear products on their roads.

Would food irradiation increase the amount of radioactive material that must be disposed?

After 15 or 20 years, the energy level of the cobalt-60 isotope becomes too low to be useful for large operations. It is likely that irradiation operators will want to remove the old isotopes to make room on the source plaque for new source material. The old isotopes emitting low levels of radiation are not likely to add significantly to storage volume of low level radioactive waste because in many cases the decayed sources can be reactivated or recycled for other industrial uses. For example, AECL offers to take back its spent cobalt pencils.

The small size of the cobalt pencils means that any cobalt-60 that is not able to be recycled would be a minute portion of the approximately 2.68 million cubic feet of low level waste disposed in 1984 (Anon., 1985c). 6/ Also, cobalt-60 from radiation therapy uses requiring intense doses can be recycled to the lower level uses needed by a food irradiator. Therefore, it is possible that low level radioactive waste disposal of cobalt-60 could decline with use of food irradiation.

Like cobalt sources, the DOE cesium-137 capsules are relatively small and net addition to low level radioactive waste is not the issue. The slower decay rate of cesium-137 means a longer period between reloadings compared to cobalt. However, cesium-137 in the DOE capsules is in a water soluble form which means a leaking or ruptured capsule could contaminate any water in the

6/ An AECL pencil contains between 6,000 and 10,000 curies and is about a half-inch in diameter and 18 inches long (Wilson, 1986).

environment around it. 7/ Thus, special precautions must be taken when using, transportating, and storing cesium.

Critics of food irradiation question the adequacy of DOT and NRC regulations for transporting radioisotopes on highways and using them in commercial facilities. They point to past accidents involving radioactive materials that have been lost or improperly disposed (Tucker and Alvarez). These opponents contend that the environmental impacts and dangers from leaking sources or unauthorized disposal of spent sources have not been sufficiently addressed.

Facilities using machine-produced ionizing radiation would not add to the amount of radioactive materials being shipped across highways or to the disposal of low level radioactive waste.

Can U.S. firms supply irradiator design and equipment?

Yes. During this study, the authors talked with presidents and engineers of five companies who designed and built their own gamma irradiators. These companies are contract sterilizers who irradiate a variety of nonfood products for individual customers. Some of these companies also have processing routines for handling food products. Another indication of the ability of U.S. companies to build irradiators is the fact that a dozen U.S. engineering and irradiation companies submitted bids to build DOE's agricultural commodities irradiator. One of the important components in both gamma and electron irradiators is a relisble conveyor that moves the product past the radioisotope or electron beam at the proper speed. There are many U.S. firms with expertise in product movement engineering.

One potential deterrent to a prospective user of irradiation designing the facility is buying cobalt-60 under warranty from AECL. The AECL warranty requires a visit to the plant to check out the cobalt-60 handling and storage procedures and equipment. AECL justifiably wants to be sure the cobalt pencils will not be mishandled since AECL intends to be liable for any defective sources. But some designers of irradiation equipment may not want AECL to see their novel approaches to radiation processing.

Machine sources of radiation require sophisticated electron accelerator equipment. Three U.S. companies build this specialized equipment for industrial processing. The size and power levels of these machines are discussed in the chapter on machine sources of radiation. Customers for these machines include 3M Corporation, W.R. Grace and Company, and Goodyear Tire and Rubber. Although most material treated with high energy electrons is handled by an in-house machine, smaller jobs and preliminary research occurs in contract facilities.

7/ Cobalt-60 is a non-water soluble metal.

Will irradiation enhance food exports or imports?

A technology that increases shelf life extends the geographic market for the fresh product. A longer shelf life provides extra time to reach distant markets or the use of a slower, and thus cheaper, mode of transportation. Irradiation may allow longer distance shipping of U.S. commodities abroad, provided the recipient country will accept irradiated food. At the same time, irradiation could allow other countries to expand their exports to us. Researchers at the National Marine Fisheries Service point out that successful application of irradiation would allow Canada, Iceland, and Norway to increase the amount of fresh fish fillets they ship to the United States (Kaylor, et. al., 1985, p. 6).

Another way irradiation could expand international trade is by disinfesting products prohibited from being imported because of quarantine restrictions. This usage also depends on the importing country accepting the irradiation treatment.

Will irradiation affect the economic structure of the U.S. food industry?

The introduction of a new technology can lead to significant changes in the number and size of firms within the affected industry, particularly if that technology significantly reduces unit costs of production, creates a new product, or adds special appeal to an existing one. Firms that are quick to adopt such a technology enjoy an edge in profitability for existing products, or they may gain an opportunity to establish new markets or capture a larger share of existing markets.

To the extent that irradiation might replace existing technologies to preserve food, it could affect the structure of some industries. It was beyond the scope of this study to compare the economic feasibility of irradiation with other technologies. Based on our analysis of treatment costs, it does not appear that irradiation will dramatically alter food preservation practices. However, changes in consumer preferences or in food safety regulations could change the economics of irradiation. For example, if new regulatory measures prohibited use of important chemical preservatives or fumigants, the competitive stance of irradiation increases. Renewed interest in food irradiation within the past two years was partially inspired by the EPA's banning of ethylene dibromide (EDB) as a disinfestation treatment for food.

Food irradiation could also provide a competitive edge to adopting firms if consumers not only accept the technology, but come to prefer it over other methods of food preservation. Irradiated foods may gain appeal on grounds of health and safety, perhaps by reducing the risk of salmonella poisoning or by substituting for chemical preservatives.

Our analysis of economies of scale, combined with information about current industry structure, provides some insight into the potential effects of irradiation on future industry structure. Chapter V discussed treatment costs for five applications using various sizes of cobalt-60 irradiators. Average costs per unit of output were found to decrease as the size of the irradiator and the amount of product being treated increased. However, this relationship becomes less dramatic at annual volumes greater than 50 million

pounds. As the size of an irradiator increases, cobalt-60 becomes a larger portion of total costs. Fewer scale economies are possible because cobalt-60 needs are directly related to the amount of product treated per hour. Therefore, two irradiators treating 100 million pounds of food a year could treat the food for about the same average cost as one irradiator processing 200 million pounds. 8/ Thus, an industry composed of fairly large firms would not have to fear that economies of scale for food irradiators would trigger rapid consolidation.

In the United States, there are many small hog slaughtering and fresh chicken processing plants that account for only a small portion of total production (see tables V-11 and V-12). Eighty to 85 percent of U.S. production occurs in medium and large plants which have sufficient volume to realize the production economies of scale for gamma irradiation.

A similar examination of the size distribution of packing plants in other food industries would give an indication of their economic compatibility with gamma irradiation. Other industries may be less concentrated and individual plants may handle smaller volumes. For irradiators treating less than 50 million pounds a year, size has a greater effect on average treatment costs (see table V-7). However, individual growers often join together in a cooperative which may have sufficient volume to justify an irradiator. Another option is to locate a contract irradiator at a port or in the center of a growing area where it could treat appropriate agricultural products on a fee basis.

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Irradiation is likely to continue to be used initially in United States for foods that are small components of the diet, such as spices and dried onion and garlic powders. These items are ingredients in processed food, and they are not disclosed on the retail label. Also, the small amount consumed may reduce any perceived risk by consumers and regulators. These items tolerate irradiation well (in fact, it preserves flavor and color better than conventional methods), they are high-valued products, and they can easily fit into the current operating procedures of contract irradiators. By using the services of a contract irradiator, a food company can test technical feasibility and consumer acceptance without undertaking the large investment of an in-house irradiator. Irradiation's use on other irradiation-compatible products will depend on regulatory approval, processor and consumer interest and acceptance, and its cost competitiveness with alternative techniques.

No technology is costless or without risk. Prospective users and consumers, as well as policymakers, must decide whether food irradiation has a place among other postharvest techniques for making the world's food supply more plentiful, varied, and safe.

8/ The relationship between treatment costs and irradiator size for facilities using machine-produced radiation was not examined by the authors.

XI. REFERENCES

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November 25, 1985

Hon. Berkley Bedell, Chairman
Congress of the United States
House of Representatives
Washington, DC 20515

Dear Mr. Bedell:

H.R.696, a bill which would change the classification of food irradiation from an additive to a process, will soon be discussed in the Department, Operations Research and Foreign Agriculture Subcommittee of the House Committee on Agriculture. The purpose of this bill, sponsored by Congressman Morrison, is to promote understanding and acceptance of food irradiation. While I do not disagree with the spirit of the bill, it fails to address the very important issue of notice to the consumer of which foods are irradiated.

I do not object to classifying irradiation as a process, so long as packages of irradiated foods clearly disclose that this process was used. This is analagous to pasteurized milk: when the process is used, the package conspicuously indicates so, and consumers know what they are buying. Consumers have a right to choose whether or not they care to purchase irradiated foods. This right is meaningless if they are unable to determine which foods have been irradiated.

Additionally, there is some evidence that irradiation alters the quality of food. Most growers of citrus fruits, for example, do not use irradiation because it damages the peel of citrus fruits and decreases their quality. Companies that irradiate food should put consumers on notice that the quality of the product they are purchasing may have been affected by irradiation. Experience will teach consumers whether irradiated foods are better or worse.

I make no judgement as to the health and safety implications of using radiation to preserve and disinfect foods, although reputable groups such as the Center for Science in the Public Interest (who sounded an early warning on the dangers of sulfite) have indicated a potential for risk. I simply ask that when this process is used, the consumer be made aware.

Given the uncertainties within the scientific community regarding the safety of food irradiation, this notice is essential.

H.R.696 provides for a Joint Operating Commission for Food Irradiation, intended to foster acceptance of food irradiation by acting as an intermediary between industry, government and the public. The involvement of industry and government is clear. It only remains to involve the public, which can best be accomplished by identifying those foods which have been irradiated. If H.R.696 is sincere about promoting understanding of food irradiation, a labelling requirement on all packages of irradiated food is essential.

Sincerely yours,

Ralph Goldstein

Ralph Goldstein
Member of Assembly

RG:eg

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INSTITUTE OF FOOD TECHNOLOGISTS

CALVERT L. WILLEY, EXECUTIVE DIRECTOR
HOWARD W. MATTSON, ASSOCIATE EXECUTIVE DIRECTOR

Mr. Chairman and distinguished members of the subcommittee:

Thank you for the opportunity to comment on HR 696, a bill to provide Federal coordination for the continued development and commercialization of food irradiation.

I am Richard A. Greenberg, Director, Office of Scientific Public Affairs, of the Institute of Food Technologists (IFT). IFT is a non-profit scientific society of more than 25,000 individuals. Our members are concerned with food science, which attempts to understand the scientific basis underlying the efficient provision of a nutritious, safe and acceptable diet. We also work in food technology, which applies this basic knowledge to the practical development of new and improved food sources, products and processes, their proper utilization by industry and the public, and their effective regulation by government agencies. Most of the scientists who have ever worked on food irradiation in the United States have been (and still are) members of IFT. We thus believe that it is particularly appropriate for IFT to comment on HR 696.

Dr. William Marion's testimony in behalf of C.A.S.T. before you today also represents IFT in his capacity as co-chairman of our Committee on Research.

IFT applauds the provisions and aims of HR 696. Irradiation processing is an idea whose time not only has come, but is long overdue.

We attach, for the record, "Radiation Preservation of Foods", a Scientific Status Summary published in 1983 by IFT's Expert Panel on Food Safety and Nutrition. Its summary states, in part, "If and when the government grants approval to produce and market irradiated foods, it will not assure commercial success. Irradiation of foods must be seen as useful enough by processors to justify the costs of the equipment needed and the process. The cost of irradiated foods to the consumer must also be competitive with the cost of foods produced by alternate processing technologies, or they must satisfy some other perceived consumer need at a reasonable cost, if they are to be accepted and successful in the marketplace."

HR 696 constitutes a giant step in fulfilling the needs of both processors and consumers in realizing the successful application of this useful technology.

Richard A. Greenberg

Richard A. Greenberg, Ph.D.
Director
Office of Scientific Public Affairs
Institute of Food Technologists

(Attachment follows:)

Radiation Preservation of Foods

A Scientific Status Summary by the Institute of Food Technologists' Expert Panel on Food Safety and Nutrition.

□ IN-DEPTH FOOD IRRADIATION STUDIES in the United States began in the early 1950s, when both radiation sources and processing equipment were developed to a practical point. Most of the studies have been government sponsored, at least partly because the 1958 Food Additives Amendment to the Food, Drug and Cosmetic Act required advance approval from the Food and Drug Administration (FDA) before any particular irradiated food could be publicly sold. Earlier work (1947-1952) was carried out by at least three private companies in the United States.

A similar circumstance prevailed in other countries, resulting, world-wide, in predominantly government-sponsored food irradiation research programs. Because of the lack of research facilities in many third-world countries, specialized agencies of the United Nations also became actively involved in international food irradiation research programs (Goresline, 1982).

Currently, two events have served to renew interest in food irradiation processing:

Recommendations by the Joint Expert Committee on Wholesomeness of Irradiated Foods, convened by the World Health Organization (WHO 1981). After reviewing all the food safety data available, this committee concluded that any food irradiated to an average "dose" of 1 Mrad (see glossary for definition) or less is wholesome for humans and therefore should be approved without further testing.

The WHO Joint Expert Committee deferred general recommendations for foods irradiated at higher radiation levels until data from on-going studies are available for evaluation.

Consideration by FDA for new regulatory procedures regarding irradiated foods (FDA, 1981). The FDA has outlined a number of possible actions which could ultimately lead to approval for irradiation preservation of foods when the irradiation levels used are 0.1 Mrad (1 kGy) or less. The FDA has also suggested changes in the criteria for establishing the safety of foods that would be irradiated at levels between 0.1 and 1.0 Mrad (1–10 kGy), which includes levels sufficient to pasteurize foods.

The recommendations of the WHO Joint Expert Committee and the regulatory procedures under consideration by FDA suggest that consideration for commercialization of irradiation preservation of foods is timely. However, the success of these processes will depend ultimately upon their costs, consumer acceptance, and labeling requirements, as well as evaluating whether the technology fulfills a perceived consumer need.

Applications to Food Preservation

The radiation preservation of foods is considered a "cold" process because there is only a slight temperature rise in the food during preservation processing. This feature makes the process attractive for heat-sensitive aspects of food processing such as nutrient retention. With only the small temperature rise associated with radiation, adverse changes in the food, such as altered flavor, odor, color, texture, and loss of nutritional quality are minimized. The irradiated food, therefore, retains more of the appearance, taste, and quality characteristics of fresh raw food.

Another advantage of these processes is flexibility. Irradiation can be used to preserve a variety of foods in a range of sizes and shapes—crates of potatoes, flour in 50- or 100-pound sacks, entire roasts of meat, whole turkeys, sandwiches of sliced meat, fish, or chicken (Josephson, 1970). This wide range of application makes

irradiation applicable to both present and anticipated industrial methods. Some of the potential applications of radiation preservation of foods are shown in Table 1.

Radiation Pasteurization

Most predictions are that the most likely applications for radiation in food processing will be to extend the shelf-life of foods before spoiling. Radiation processing can also be used to destroy or inactivate disease-causing organisms carried by foods. Radiation pasteurization produces food products similar to the familiar products that have been pasteurized by heat (except that radiation-pasteurized foods are not cooked); as would be expected, refrigeration is also generally required for radiation pasteurized products. As in heat pasteurization, the food products' shelf life is extended considerably.

The extension of shelf-life for these radiation-pasteurized foods results from reducing the number of food-spoilage organisms, such as bacteria, yeasts and molds, that can be present. Thus, radiation pasteurization makes it possible to ship foods like chilled, unfrozen seafood from the coastal places of catch to the central parts of the continent (Ronsivalli *et al*, 1969).

Radiation pasteurization is also effective in preserving fresh meat, poultry, or other foods that can harbor organisms causing food-borne *illness*. For example, radiation pasteurization of poultry, poultry products, and poultry feed is a simple and yet effective way of controlling contamination with *Salmonella* (Froning, 1978; Kampelmacher, 1982; Mossel and Van Netten, 1982). Even in the developed countries, *Salmonella* contamination can be serious enough that some health authorities have suggested that radiation pasteurization should be required, to bring the problem under control (Ouwerkerk, 1981).

Radiation Sterilization

Another possible application of radiation to food processing is as a means of preparing "commercially sterile" food products. Depending on the food, spoilage and disease organisms are killed at radiation doses of 1–5 Mrad (10–50 kGy). Such foods, therefore, can be stored like their heat-sterilized (canned) food counterparts. Like canned food, radiation sterilized foods can be stored for years without refrigeration, as long as the food package is not punctured or corroded. Radiation-sterilization studies carried out so far have been limited essentially to meats and certain seafoods. The level of radiation needed to produce a commercially sterile product will vary with the food that is to be processed and the processing conditions, just as the amount of heat needed in canning varies. The required level is determined by test with spores of *Clostridium botulinum* inoculated experimentally into the same food.

Before the actual radiation processing, the food typically is first heat treated (blanched) to inactivate any autolytic enzymes present, as is done for frozen foods. This helps assure that there will be no enzymatic spoilage after radiation treatment. (Josephson, 1981). This heat treatment also inactivates some food-borne viruses (Larkin, 1977), helps to drive out oxygen, makes some radiation-resistant organisms more sensitive (Firstenberg-Eden *et al*, 1980), and serves to cook the food as well. For example, beef steak or roast beef will be cooked to a "medium" degree of doneness. The prepackaged food is then sealed under high vacuum to remove remaining oxygen, frozen to −40°C (−40°F), and irradiated to about 1–5 Mrad (10–50 kGy) (while frozen) for preservation. The freezing step acts to minimize further the possibility of flavor changes or nutrient loss during irradiation. After irradiation, the packaged food is allowed to thaw and can be stored

Glossary

Electron Radiation. Corpuscular radiation, consisting of streams or beams of electrons accelerated to energies of up to 10 MeV. There are a number of machine sources available for electron radiation.

Gamma Radiation. Electromagnetic radiation of a very short wavelength, of the same nature as "short" X-rays. Gamma rays are emitted by isotopes of such elements as cobalt and cesium as they disintegrate spontaneously.

Gray (Gy). The unit (or level) of energy absorbed by a food from ionizing radiation as it passes through in processing. 1 Gray (Gy) equals 100 rads; 1000 Gy equals 1 Kilogray (kGy).

Rad. Another name or unit for "radiation energy absorbed" by food being processed with radiation. 1000 rads = 1 Kilorad = 10 Grays (see above); 1,000,000 rads = 1 Mrad = 10 kGy
(The rad is being superseded by the Gray.)

Radappertization. Sterilization by radiation processing. The resulting processed food can be stored at room temperature, in the same way as thermally sterilized foods (canned foods). Precooked food in hermetically sealed packaging is exposed to radiation at levels high enough to kill all organisms of food spoilage or public health significance. Doses used are typically greater than 1 Mrad.

Radicidation. Radiation pasteurization intended to kill or render harmless all *disease-causing* organisms (except viruses and spore-forming bacteria) in food. Processing takes place at dose levels generally below 1 Mrad, and the processed foods usually must be stored under refrigeration (as in heat pasteurization).

Radurization. Radiation pasteurization designed to kill or inactivate *food-spoilage* organisms, thus extending the shelf life of a given food product. Again, processing takes place at dose levels generally below 1 Mrad, and the product usually must be stored under refrigeration, as in the case of radicidized food (see above).

X-rays. Electromagnetic radiation of a wide variety of short wavelengths. They are usually produced by a machine in which a beam of fast electrons in a high vacuum bombards a metallic target. X-rays are sometimes called "Roentgen rays," after their discoverer, Lord von Roentgen.

Table 1.—APPLICATIONS OF RADIATION PRESERVATION TO FOOD *(FAO, 1965)*

	Food	Main objective	Means of attaining objective
Above 1 Mrad	Meat, poultry, fish and many other highly perishable foods	Safe long-term preservation without refrigerated storage	Destruction of spoilage organisms and any pathogens present, particularly C. botulinum
	Spices and other special food ingredients	Minimization of contamination of food to which the ingredients are added	Reduction of population of microbes in special ingredient
Below 1 Mrad	Meat, poultry, fish and many other highly perishable foods	Extension of refrigerated storage below 3°C	Reduction of population of microorganisms capable of growth at these temperatures
	Frozen meat, poultry, eggs, and other foods, including animal feeds, liable to contamination with pathogens	Prevention of food-poisoning	Destruction of Salmonellae
	Meat and other foods carrying pathogenic parasites	Prevention of parasitic disease transmitted through food	Destruction of parasites such as Trichinella spiralis and Taenia saginata
	Cereals, flour, fresh and dried fruit, and other products liable to infestation	Prevention of loss of stored food or spread of pests	Killing or sexual sterilization of insects
	Fruit and certain vegetables	Improvement of keeping properties	Reduction of population of molds and yeasts and/or in some instances delay of maturation
	Tubers (e.g., potatoes), bulbs (e.g., onions), and other underground organs of plants	Extension of storage life	Inhibition of sprouting

without refrigeration (Josephson, 1982).

Advantages of Radiation Processing

The conventional thermal canning process has some disadvantages: foods generally need to be packed with liquid, to assure better heat penetration and relatively small containers give the best results; disruption of cell walls in the food by heat generally leads to processed products with softer textures and altered flavors (Josephson and Wierbicki, 1973). Radiation processing, on the other hand, produces shelf-stable products that are closer to the fresh state in texture, flavor, and color. Other advantages possible through radiation processing include: the product can be packed dry; there is no loss of natural juices during radiation processing; larger container sizes can be used; better portion control in packaging is possible. With radiation processing, it will also be possible to prepare new shelf-stable products such as corned beef briskets and pork sausage.

In flavor tests, the irradiated shelf-stable meats and seafoods developed by the U.S. Army scored well within the acceptable range. Irradiated products, such as radappertized ham, were eaten by the Apollo astronauts on the moon and by the American astronauts and Russian cosmonauts participating in the joint American-Soviet Apollo-Soyuz space flight in 1975. During the Columbia space shuttle flights, American astronauts ate radiation-sterilized meats such as beef, pork, smoked turkey and corned beef. Radiation-sterilized food products have been approved for use for the special hospital meals needed by patients who must have sterile foods because their immunity to disease has been altered by medical treatments. A massive study on the wholesomeness of radappertized (radiation-sterilized) chicken, begun in 1976, has recently been completed. The data are now being evaluated by the U.S.D.A. for their sufficiency to support a petition to the F.D.A.

Other Food Irradiation Applications

Irradiation can be used instead of chemical fumigation to control the insect infestation that can occur in cereals, flour, fresh and dried fruit and other food products vulnerable to insect attack. For example, irradiation is effective in sexually sterilizing or destroying the Mediterranean fruit fly (Medfly).

Spices and other special food ingredients can have high bacterial loads because of the growing and handling practices in the countries of origin. When added to foods, these ingredients may serve as sources of contamination with spoilage and disease organisms. The safety of chemical fumigants has been questioned, and heat cannot be used for spices as a decontamination method because it drives off the volatile substances responsible for the characteristic flavor and odor of the spice. Radiation, however, *can* be used to decontaminate these special food ingredients because it is a "cold" process. Thus, radiation decontamination could prove useful in protecting the true flavor and odors of spices.

The use of radiation at levels of 0.003–0.015 Mrad (30–150 Gy) or less to inhibit sprouting of tubers (e.g., potatoes) and bulbs (e.g., onions) and thus extend storage life has been approved in the U.S., Japan and other countries. This is especially important in northern countries which do not permit chemical antisprouting agents to be used on their single crop of potatoes; irradiation can inhibit

sprouting and provide the population with whole potatoes throughout the year, without the usual price escalation or the expense of imported potatoes. Although an after-cooking darkening of the potato can occur (Matsuyama and Umeda, 1982), this does not seem to be of serious concern.

Irradiation treatment can also replace some food additives, or reduce the amounts required. For example, irradiated ham, bacon, corned beef and other cured meats have been produced with much less nitrite than is used in conventional cured meats, and are indistinguishable in flavor from commercially produced counterparts. Scientists have also produced corned beef, frankfurters and bacon without *any* nitrite (Wierbicki, 1979; Wierbicki and Brynjolfsson, 1979; Wierbicki and Heiligman, 1980)—although most of the processed products are not pink and have a slightly different flavor. Nitrite not only gives cured meat its characteristic pink color and flavor, but—most importantly—it inhibits the production of botulism toxin. Since radiation kills *C. botulinum* cells, it can replace nitrite as an anti-botulism agent, thereby significantly lowering the amount of nitrite added to only that amount required to develop the normal pink color and cured meat flavor.

Considerations About Wholesomeness

Four important areas that should be considered in discussing the wholesomeness of irradiated foods include:

1. Is measurable radioactivity induced in the food products by the process?

2. Are any pathogens present destroyed?

3. Are toxic radiation products (radiolytic products) produced?

4. Are there unacceptable losses in nutritive value?

Radioactivity occurs naturally in all foods. If cobalt and cesium are the only isotopic radiation sources permitted for food processing, the maximum gamma ray energies will be below the threshold level that would otherwise induce radioactivity in food. Similarly, if the maximum energies of electron beam and X-ray sources are restricted, no measurable induced radioactivity in the food will occur. Thus, the expected question "Will this make the food radioactive?" can be answered "No." Any radioactivity present will be "background radiation," already present naturally. Equipment and processes for safely using the radiation sources mentioned above are well established.

As mentioned above, the irradiation process proposed to yield radiation-sterilized food combines the use of radiation levels sufficient to destroy the spores of *C. botulinum* with pre-heat treatment (blanching) for enzyme inactivation. This dual treatment is sufficient to destroy microbiological, viral and parasitic organisms in the food, effectively eliminating the potential hazard of food-borne pathogens.

The use of ionizing radiation in food processing, like the presently used commercial processes of freezing, canning and drying, produces no significant reduction in the nutritional quality of the protein, lipid, carbohydrate and mineral constituents (Josephson *et al*, 1978). Irradiation, moreover, is comparable to presently used food preservation processes in its effects on vitamins, although nutritional effects vary with the dose of radiation. Pork treated with irradiation processing, for example, retains more of its thiamine than when canned (Thomas *et al*, 1981). In radiation sterilization processing, retention of nutrients is improved by the low temperature used during the processing, and the reduction or exclusion of oxygen from the package helps prevent destruction of vitamins.

Proper packaging is crucial to radiation processing of foods, especially for radiation sterilized foods. Specific packaging materials have been approved as food contactants by the FDA for radiation processing of food (Josephson, *et al*, 1975). Containers for irradiated foods have been tested for stability and integrity and will be approved on the basis that they will provide the same stability qualities as the packaging materials used for more traditional food packaging systems.

Testing for Safety and Wholesomeness

To date, testing of wholesomeness of irradiated foods has been based largely on the complicated biochemical and biomedical tests associated with long-term feeding studies, with two or even three species of animals. To get approval in the United States for irradiation of a particular food under the 1958 Amendment to the Food, Drug and Cosmetic Act, such data has to be submitted to the FDA. Between 1959 and 1981, approximately 40 irradiated foods have been approved by health authorities in at least one of 24 countries having legislation on irradiated foods (van Kooij, 1982). This includes, in the U.S., radiation processing for disinfestation of wheat grains and sprout inhibition for potatoes.

Recently, the FDA has suggested that irradiation be treated as a *process*, and that information gained about the radiation chemistry of components of *one* food can be used to evaluate the effect of irradiation on other foods of similar composition. This would greatly reduce the need for individual testing of foods, but should not compromise the health of anyone consuming approved irradiated foods. Many irradiated foods have been examined for chemical products (radiolytic products) which irradiation may have formed in the foods, and on possible toxicologic significance of such products. A considerable body of scientific knowledge on radiolytic products has been developed in recent years. In one study of meat (Merritt *et al*, 1978), the radiolytic products that were identified have also been found in *non*-irradiated foods, either processed or unprocessed. Whether this is true for all other foods is not known, but no other compounds have been identified to date.

The absence of toxic products resulting from food irradiation has been established on scientifically firm ground. The chemistry studies, animal feeding studies, tests for mutagenicity and tests for teratogenicity have revealed no confirmed negative evidence as to the wholesomeness of radiation preserved foods. Significantly, whenever adverse findings were originally reported in the literature, re-testing failed to confirm the original adverse reports. In fact, in some instances, analysis showed that the reports of unusual findings were *not* the result of factors specifically related to the irradiation proposed for commercial application. Thus, we should be able to assess wholesomeness more

generally by applying the information developed about one food to related foods. This process is called "chemiclearance."

The Joint Expert Committee convened by WHO In 1980 reported that sufficient data are now available to conclude that all major classes of foods irradiated up to an average dose of 1 Mrad (10 kGy) pose no toxicological problems, and could be permitted for use by humans without further testing for wholesomeness (WHO, 1981). The international organization concerned with food standards, the Codex Alimentarius Commission of the United Nations FAO has also endorsed these recommendations.

Five important principles underlie their conclusion:

- Irradiation is a process with uniform and predictable changes;
- Radiolysis products pose no short-term or long-term toxicologic hazards based on feeding studies in standard mutagenic tests;
- Irradiation introduces no special microbiological problems;
- Nutritional quality is not compromised; and
- Irradiation levels used in specific applications should be consistent with the objective (sterilization or pasteurization) and the requirements set by the regulatory authorities.

Acceptance by health authorities of the principles enunciated by this international group of experts should speed up world-wide approval of irradiated foods.

Regulation of Irradiation Processing

With the development of more sophisticated toxicological testing methods and a firmer scientific base of understanding of irradiation processes and radiolytic products, the FDA has now put out an "advance notice" that it will propose evaluation of a more general approval system for foods irradiated at 0.1 Mrad (1 kGy) or less. This is more conservative than the WHO-suggested limits of 1 Mrad. The FDA has also suggested specific tests for the scientific evaluation of any chemical compounds formed in food when higher levels (0.1–1.0 Mrad (1–10 kGy)) are used to irradiate foods, rather than using the WHO chemiclearance approach. These tests include both 90-day animal feeding studies and a battery of short-term tests to assure that radiolytic substances do not cause genetic changes. Spices, under the FDA proposal, can probably be irradiated at a higher level than other foods, because they are generally used in such small amounts. The amount of any unidentified radiolytic product can be considered insignificant.

Labeling requirements for irradiated food products are also being considered. Under the original concept that radiation was to be considered as a food additive, its use would have had to be spelled out in the ingredient listing of each processed food. Preservation *processes* currently in use, however, do not now have to be specifically listed on the labels (whether canned, frozen, or dried); the same philosophy might apply to *radiation* processing. Comments on labeling aspects have consequently been requested in the FDA proposal.

Under the current law, FDA must also approve the food packaging materials that come in contact with the food as well as the package itself before either can be used commercially. The first step regarding radiation processed food packaging has been taken: FDA has already approved a number of *materials* for use in contact with food.

To prevent the possibility that radiation pasteurization might lead to the development of radiation-resistant microorganisms, suggestion has been made that repeated irradiation of a food be prohibited. FDA plant inspections and record examinations would enable the agency to enforce such requirements. However, the WHO Joint Committee recommended that re-irradiation be permitted, where needed, at least to a cumulative dose of 1 Mrad (10 kGy).

Summary

Since World War II, research has brought the process of food irradiation preservation to the point of commercial application. The process is versatile and has the potential to provide more food, of good taste, with fresh-like quality and of wholesome and nutritional value to consumers, at projected costs (in money and energy) that should make it competitive with older food processing methods. This should make food irradiation preservation a commercially attractive technology.

After years of testing for the wholesomeness of irradiated foods, international review has concluded that products irradiated to an average dose of up to 1 Mrad are wholesome. The report of the WHO Joint Expert Committee has recommended approval of food irradiation processing. The FDA has opened a dialog on recommendations for such processing and has asked for comments re possible regulatory guidelines and limits for such use.

Between 1958 and 1981, some 40 irradiation-processed foods have been approved for human consumption by national health authorities in at least one of 24 countries. For doses greater than 1 Mrad (10 kGy), data compiled from a massive 6-year study on the wholesomeness of radappertized chicken are now being analyzed by the U.S.D.A. to determine whether it is sufficient to support a petition to the F.D.A. for approval.

If and when the government grants approval to produce and market irradiated foods, it will not assure commercial success. Irradiation of foods must be seen as useful enough by *processors* to justify the costs of the equipment needed and the process. The cost of irradiated foods to the *consumer* must also be competitive with the cost of foods produced by alternate processing technologies, or they must satisfy some other perceived consumer need at a reasonable cost, if they are to be accepted and successful in the marketplace. The day for that ultimate test may soon be upon us.

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PUBLIC VOICE FOR FOOD & HEALTH POLICY

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STATEMENT OF
PUBLIC VOICE FOR FOOD AND HEALTH POLICY
IN CONNECTION WITH
HEARINGS HELD ON NOVEMBER 18, 1985
BEFORE
THE SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH AND FOREIGN AGRICULTURE
OF THE AGRICULTURE COMMITTEE OF THE
HOUSE OF REPRESENTATIVES
REGARDING FOOD IRRADIATION

Mr Chairman, Public Voice submits these comments because we have long been concerned about unresolved critical questions regarding the use of ionizing radiation to treat foods and the critical need for adequate labeling for any foods that have been irradiated. Public Voice for Food and Health Policy is a non-profit organization concentrating on food safety, nutrition and agriculture policy.

It is our belief that the sweeping changes and conclusions of H.R.696 are premature and unjustified at this time. The legislation would amend the Food, Drug and Cosmetic Act to redefine "Food irradiation" as a food process rather than as an additive, provide national unformity in the regulation of food irradiation and establish a commission within the Department of Agriculture to promote the use of food irradiation. Until more is know about the long-term effects of food consumption of irradiation products, only restricted use of low-level irradiation as a food processing technology should be permitted on a product by product basis. Additionally, with the use of irradiation, there should be concommitant labeling with words alerting consumers that the food item was treated with irradiation.

Food irradiation promises many desirable advantages over current processing alternatives: sterilization, elimination of harmful bacteria, retardation of mold growth and maturation in fruits, and prevention of sprouting in vegatables. But food irradiation only promises these benefits, and cannot guarantee freedom from harmful consequences. Public Voice is particularly concerned about the unresolved issue of the unique radiolytic products (URP's) URP's are produced during irradiation and remain in the food as it travels through the food chain. Despite the fact that several reports (among them the 1980 Bureau of Foods Irradiation Food Committee (BFIFC)) have concluded that levels of URP's in food irradiated at doses of 100 krads or less are "wholesome and safe for human consumption" without toxicological testing, we believe major unanswered questions remain:

-what are the long term effects of URP's on the human system?

-have all possible URP's been detected and identified?

-what is the increased burden on the human population of URP's from food irradiation?

-to what extent are cumulative concentrations of URP's innocuous in cases of unauthorized re-irradiation?

Another concern about the effectiveness of irradiation is its lack of a continuing preservative effect: after a time, irradiated foods are vulnerable to reinfestation by bacteria and insects. In addition, since most foods could be irradiated after packaging, safety questions may come into play when sealing

and packaging materials break or tear. Another health consideration, which apparently relates only to packaging materials following doses of over 1 Mrad, is the possible migration of toxic materials from package to food in irradiated products. This problem could be compounded by repeated applications of irradiation.

The Consumer Perspective

Public Voice strongly supports the labeling of irradiated products at the retail level in order to alert consumers to products which have undergone irradiation treatment and to ensure that they are not mislead by the absence of labeling information to think that the food has undergone only traditional processing. Labeling information is also necessary to facilitate recalls of irradiated food in the event health problems are discovered.

In this position, we join our consumer organization colleagues in Europe, where the use and study of irradiation has been more widespread. In addition to the pro-labeling position taken by the Bureau European Des Unions De Consommateurs (BEUC), the coalition of consumer groups in the European Economic Community. Public Voice's views on labeling also correspond to early work on the issue by the EEC Commission as well as later standards under development by the Codex Alimentarius.

Consumers need full information to make food choices

Food labels provide a mechanism for consumers to determine the appropriateness of certain product selections in terms of further preparation required, health value and safety. Fresh, frozen and canned/heat-processed foods can readily be accessed

as such, but since irradiation is a new concept to most consumers, questions are likely to be raised about consuming irradiated foods. Furthermore, because the safety of the process has not been clearly established and because the impact on nutrient value for certain population groups could well be significant, information on irradiation treatment should be noted on product labels.

Only by exercising one's right of choice in the marketplace can the consumer choose the amounts of processed and unprocessed foods he or she consumes, and determine the amount of irradiated products he or she wishes to purchase. Public Voice believes it is essential to take action to enable consumers to exercise the right to choose the foods they desire with clear information of the use of irradiation declared on the label at the retail level.

For the foregoing reasons we:

--oppose H.R.696,

--believe more research is necessary on URP's, and

--call for mandatory labeling of all food products treated with irradiation.

Respectfully Submitted,

Ellen Haas

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FOOD IRRADIATION PROGRAM

The Port of Pasco is pleased to supply this information about the Food Irradiation Program. The Port of Pasco applied to the Secretary of Energy on May 7, 1984, for the establishment of a food irradiation facility to utilize the residual waste cesium-137 currently stored at the Hanford Nuclear Reservation to process agricultural products from the Columbia Basin and the Pacific Northwest. We have been working with the ByProducts Utilization Program, Energy Technologies Division, Albuquerque DOE; Battelle Northwest Laboratories and CH2M Hill.

The irradiation process may become an important factor in developing new export markets for major Northwest agricultural products such as apples and cherries. It may also become important to domestic markets as it may serve as a replacement for chemical fumigants which have been subject to adverse findings regarding their safety. Irradiation has been proved to be a safe and wholesome method of disinfestation, fumigation, and preservation of food products. A joint expert committee of the UN Food and Agriculture Organization, the International Atomic Energy Agency, and the World Health Organization, has recommended that "the technological and economic feasibility of food irradiation on an industrial scale should be established."

So far, 28 countires, including Japan, Israel, France, Holland and the Soviet Union, have given unconditional or provisional clearance for the commercial irradiation of more than 50 foodstuffs, according to the IAEA. The foods cover vegetables, poultry, fish, grains and fruit. About 100 food irradiation plants currently are operating worldwide.

Some useful side benefits have been found, including the following:

- Winemakers in Europe have discovered that irradiated grapes yield more juice than untreated ones -- without harming the wine.
- Irradiated wheat produces bread with a greater loaf volume.
- Irradiated barley gives a 7 percent higher yield during malting.
- Dried navy beans and red kidney beans cook in less time.
- Prunes dry more quickly.
- Some meat becomes more tender.

In order for these advantages to be realized, certain federal statutory and regulatory changes must occur.

FOOD IRRADIATION PROGRAM continued -- page 2

We support the legislation introduced by Representative Sid Morrison and Senator Slade Gorton (H.R. 696 and S. 288) to promote the increased use of this process and to ensure that it will be done with adequate safeguards. The U.S. Food and Drug Administration is presently considering new regulations which would allow greater applications of irradiation in low-level dosages. The proposed regulatory changes would allow levels up to 100,000 rads, which is only one-tenth the safe level established by the Joint FAO/IAEA/WHO expert committee.

Food irradiation technology has been established around the world for more than 20 years. In this process products are exposed to controlled amounts of gamma radiation from sources such as cobalt-60 or cesium-137, two radioactive isotopes. The product being irradiated does not become radioactive. Radiation is measured in energy units called a rad. At levels of less than 100,000 rads, sprout inhibition can be achieved in potatoes and onions, and fruits and vegetables can be rid of insects. In the 100,000 to 1,000,000 rads range we can achieve extension of shelf-life, and in the range of one to five million rads commercial sterilization can be accomplished. With the low amount of thermal energy transmitted by this type of processing, it is often referred to as cold processing.

Food irradiation may open new channels for fresh fruit exports; for example, Japan currently quarantines all apples grown in the Pacific Northwest. Gamma rays have been shown to effectively control the offending coddling moth and its larvae without damaging the fruit.

The benefits to mankind from this important technology are many. It is common practice in the United States today to sterilize by irradiation many medical products and even entire diets for the protection of patients.

Food products which are irradiated and then kept in a sealed container do not need refrigeration. This procedure is used for the astronauts diet, the field rations of our Armed Forces, and it has potential in developing nations to prevent starvation.

Food irradiation can result in consumer savings, too. A study of refrigerated strawberries conducted by the Edison Electric Institute, an electrical industry group, concludes that irradiation could cut spoilage from the typical rate of 25 percent to 5 percent.

In the area of food processing the United States lags behind the rest of the world in the utilization of irradiation for fumigation and preservation purposes. Federal regulation to date has been overly restrictive regarding the process which research has demonstrated to be safe and wholesome. The proposed legislation and revised FDA regulations will provide for these new opportunities.

James L. Hayles
President

Mack L. Funk
Industrial Development Manager

KPFK 90.7FM

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Nov. 10, 1985

Congressman Leon Panetta
House of Representatives
Washington, D.C. 20515

Dear Congressman Panetta:

I am enclosing a copy of "Report to the Consumer" (#325) dealing with the hazards of IRRADIATION OF FOODS.

In September, 1984, when I aired the contents of the enclosed newsletter on my "Consumer Awareness" show, the unanimous consensus was that:

IRRADIATION OF FOODS MUST NOT BE UNDERTAKEN UNTIL THE PUBLIC IS ADVISED OF ALL OF THE TRUE HAZARDS, WHICH HAS NOT BEEN DONE EITHER BY THE FDA, HHS, or USDA!

EPIDEMIOLOGICAL STUDIES ON HUMANS, TO DETERMINE WHETHER LONG-TERM INGESTION OF IRRADIATED FOODS WILL INCREASE CANCER AND/OR GENETIC DAMAGE MUST BE DONE PRIOR TO ADOPTION OF IRRADIATION!

I urge you to vote against HR-696, when it is discussed on November 18th, and ask that this letter, and the entire RTC #325 be included in the hearing transcripts.

Sincerely,

Ida Honorof

Ida Honorof
2901 Los Flores Bl.
Lynwood, CA 90262

PS: My show is on the air for 55 minutes--with no commercial interruptions.

PPS: Please send me a copy of the transcripts of the 11-18-85 hearing. Many thanks.

Ida Honorof

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Vol XIV -Sept/84 - #325

"A Report to the Consumer"

Irradiation

Add a new buzz word to your vocabulary. It is *irradiation!*

The discovery of EDB in grain products—in everything from pasta to pancake flour—has prompted the great commercial scientists to dust off an idea that most people literate in the subject believed bypassed and forgotten years ago. In fact, an extensive literature on the subject surfaced to sour the landscape as early as the post WWII years. By the mid 1960s scientific findings had removed irradiation from consideration as food preservative for all except those engaged in the food business, or those trying to find a way to get rid of radioactive waste.

The late Dr. Granville Knight, once an *Acres U.S.A.* Conference speaker, had more than a passing interest in the irradiation process. As a competent physician, he pulled into orbit a great deal of literature on the irradiation process, some of which had been passed on to the Price-Pottenger Nutrition Foundation. The findings are so extensive that *Acres U.S.A.* can only present an abstract in-depth of a comprehensive wrap-up by Dr. Walter Herbst.

The best available wrap up on the subject appeared, under the imprimatur of a German publication, *Verlagsgenossenschaft der Waerland* as an article entitled *Incalculable Health Risks by Food Irradiation.* Herbst in turn drew on dozens of scientists who stated the case presented as the backbone of this article.

BACKGROUND

According to several scientists, the real impetus behind the irradiation concept is the fact that industrial society now has a fantastic accumulation of radioactive waste from nuclear plants. This waste product, for which no suitable disposal system has been found, is ready in the wings as a cheap source of irradiation energy. As radioactive waste continues to accumulate, those associated with both the food and atomic industry have become more emphatic in their demands on FDA. In short, those responsible for the wholesome food supply are being pressured to release more foods for irradiation.

At approximately the time of the EDB newspaper headlines, irradiation came out of the closet in *Industrial Technology* magazine. That journal had nothing but fulsome praise for irradiation on grounds that the astronauts had made use of food preserved in that manner. *Industrial Technology* said that at doses below 1 megarad, there was no danger from radioactivity or resultant carcinogens or toxins in food.

Preservation of food without destroying nutrition has been an objective of the trades since the first cartload of vegetables headed for market somewhere in the world. Even primitives knew that food—even treated food—was subject to physical and chemical changes. Accordingly, the addition of salt, sugar and smoke has been used to kill or inhibit microorganisms responsible for decay. Heat has also been used as an agency for preservation, always in the form of pasteurization or sterilization.

In the grain trade, insect and fungal attacks on marginal production are costly to commerce. Much the same is true for peas, beans and dried fruit. The appearance of EDB in chain store food products recently has the earmarks of a well choreographed background dance for the introduction of irradiation.

But what is irradiation? It is now a matter of record that GIs during the wars were used as handy test creatures whenever the Svengalis of science had new super-science to offer. Food irradiation made its debut that way, with uninformed provenders marveling at how well non-foods would keep for GIs in the field. For the purpose of food irradiation, either large-size apparatus like particle accelerators and X-ray could be used, or—in most cases—physical decay of the nucleus of radioisotopes found in atomic waste and reactors were invoked.

There is a problem in this. Unlike heating and chemical processes, radiation affects the molecule in a most specific and highly interventionary manner. It establishes "excited conditions" and induces the formation of radicals, or ionization. The molecules and atoms accordingly changed are chemically highly reactive and effect specific changes, some of which are only partially effective in preserving food. But they cause qualitative changes in foods that are—depending on dose—extremely dangerous.

In any case, talk of danger is being washed away with the intelligence that a 350 million per year industry is about to be born for spice processors alone, and that the irradiation business could expand to $1 billion per annum rather promptly. All that was needed was a trip for most food through a typical $2 million irradiation chamber. Microbes would be "killed," but enzymes would be "inactivated," if one wants to note official grammar. Those who support the concept are much worried about *Clostridium botulinum,* and they offer the consolation that 80% less nitrates will be needed in food preservation.

The industry and the musical chair directors of FDA are already arguing that irradiation is cheap. It is.

It is not extreme to suggest that a replay of the fluoridation scenario is unfolding. In the case of fluoride, the phosphate and aluminum industries found themselves with waste that was only slightly more difficult to get rid of than atomic waste. Thus was born the

Now that EDB (ethylene dibromide) has finally been labeled as a killer, the embalmed-food industry is pressing hard for irradiation as a food preservative. They would like to use radiation dosages in excess of 1,000 kilorads for long shelf "life." FDA studies show that if food irradiated at 100 kilorads comprises more than .01% of the diet, there are so many *unique* byproducts in the food that further testing should be done—*Science,* February 17, 1984.

Unique means that food compounds are no longer food compounds. What the deleterious effects of those compounds are on the body can not be separated from the effects of some of the hundreds of other unnatural compounds in the bodies of people and test animals. Once again scientists propose to use us as guinea pigs, having made reasonably certain that grounds for liability suits can not be established.

There is only one way to prevent sickness and genetic mutations from destroying us, and that is to turn to locally grown fresh foods grown and processed without chemicals. There is no longer any basis for confidence in scientists generally. We can no longer tolerate the decisions of science-for-pay.—*John D. Homaker letter.*

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bright idea of loading the toxic materials into the nation's water mains on the basis of specious scientific findings that fluoride contributed to hardness in teeth, hence less cavities.

In the case of irradiation, the surplus product that is difficult to get rid of is radioactive waste. Radioactive waste to treat a ton of potatoes, for instance, would cost only pennies, and the cost of materials to treat the rest of the groceries would be even smaller. And this is how the nuclear industry hopes to move out that tiresome waste—into thousands of food treatment facilities, into city dumps, where irradiated packages may well continue to give off their dangerous energy.

It may be that the community is willing to accept these hazards as a calculated risk. A more important question, possibly, would be: does it work?

ODOR AND FLAVOR

Commercialization of irradiation for foods has been slow because of organoleptical changes in the food due to bombardment with radiation. This means odors and flavors are depreciated by the process, and this is something the consumer will not accept. Milk and cheese have led the way in being unsaleable with less than 0.1 mrad treatment. Needless to say, technology has improved, and the industry can now use chemical additives to fool the taste buds and the human smeller.

TISSUE CHANGE

There are other changes in food when irradiation is invoked. Large molecules of the cell and permeability of these walls to different ingredient substances of the cell are especially sensitive to radiation. This means that with an increase of permeability, internal cell turgor decreases simultaneously. Adhesion of cells, one to another, is reduced. Increased respiration within the cell supports detrimental changes in the texture of irradiated foods.

RADIOMIMETIC CHEMISTRY

Now, back to the business of radiomimetic chemistry. Scientific literature has accumulated a fantastic inventory of information on this, and space conservation policies at *Acres U.S.A.* suggest that only bare notes be presented:

Cell division. If potatoes are irradiated with only 20 to 40 krad and barley seedlings are cultured in the mash of such potatoes, an increase in degenerated cell nuclei occurs in the cells of the barley.—*Swaminathan, et al.* If barley and onions germinate in orange and apple juice irradiated with 200 krad, chromosome breaks are observed in these plants during cell division.—*Chopra, et al.* The effects of extracts of irradiated plants on cell division cause an increase in mitotic disturbances.—*Kuzin, et al. Cultures of human leucocytes, to which irradiated sugar solution is added, exhibit a decrease in the rate of cell division and an increase in chromosome breaks.—Shaw, et al, from Whitehair.*

Mutations. If Drosophila (a fly species used in lab tests) are given food irradiated with only 150 krad, the number of sexually-bound recessive mutants as well as the mortality of the animals increases. Similar findings have been repeatedly confirmed.—*Swaminathan, et al; Holstein.*

Fertility. In view of more recent radiobiological results, which reveal that direct radiation has a more drastic effect on fertility assumed, it is not surprising that the fertility of the animals is reduced when they are fed irradiated food. Thus the reproduction of rats, additionally fed irradiated oranges, was disturbed in some cases.—*Phillips, et al.* The suspicion remains that if dogs are fed irradiated meat, this may cause a reduction in fertility of the animals.—*McCay, et al.*

Injuries to the embryo. Embryonal damages are almost certain to occur.

Digestibility. Irradiation generally reduces the digestibility of food.—*Schreiber, et al.*

General metabolic reactions. The consumption of irradiated foods will affect the metabolic reactions in the organism. Rats fed irradiated pork showed an increased enzymatic activity in the liver tissue.—*Read, et al; Tinsley, et al.*

Growth, vitality, morality. A considerable number of observations on the effect of irradiated foodstuffs on growth have given room for serious doubts. For instance, a significant reduction in the growth rate of the third generation of rats, additionally fed oranges irradiated with only 140 krad occurred.—*Phillips, et al.*

Hematological and immunological processes. Hematology is the branch of medicine which has to do with blood and blood diseases. Immunology is the science which has to do with immunity and the processes which lead to immunity, i.e., resistance against infections. Since the after-effects of the consumption of irradiated foods on living tissue are similar to those of direct radiation, the relevant problems, which include an eventual reduction of the resistance against infectious diseases, are of utmost importance and deserve due attention, European researchers report.

Changes of the organs. In dogs fed irradiated food, an increase in the weight of the spleen together with congestions in this organ, was determined.—*Larson, et al.*

Carcinogenicity. Some authors report a significant increase in malignant lymphomas in mice fed irradiated food.—*Reiss, et al.*

Acres U.S.A. does not present these facts as definitive. Who knows, maybe the government has repealed the laws of physics, and atomic energy is different nowadays from what it was when most of this research was done, approximately a decade and a half ago. But perhaps we can be pardoned for asking these questions.

Some of the same questions have been asked about radar range food, and the answers have not been forthcoming. Except for material printed in the foreign press, we have a hard time getting scientific answers to many things. We think it can be argued that Germany—the fountainhead of modern chemistry—is far from illiterate in the subject, and therefore their scientists must be taken seriously, even if circulation of this information is inimical to commercial interests in the U.S.

It is probably asking for a cover-up but we believe a Congressional investigation is indicated. The FDA's recent action that permits irradiation of food for the market is too irresponsible to go unchallenged.

So far FDA has approved irradiation on wheat and wheat products, and on potato tubers for sprout inhibition. Approval for spices came in July 1983. Now the agency wants to permit zapping by up to 100 krads across the board. From the sound of language now being bandied about in the agencies, irradiation beyond 100 krad will arrive very soon. Industries involved will simply have to prove that 100 krads irradiation causes no genetic suffice as proof.

Such stone age science should be beneath the dignity of a developed nation—but it isn't, not when there are $2 million irradiation chambers to be sold, and when the food industry—having shoved out the farmer—suddenly taste a $1 billion industry coming on.

SCIENTIFIC FINDINGS

According to German scientists many packing materials suffer structural changes when irradiated and become permeable to air. This endangers the enclosed foods, and sometimes delivers toxic substances to the food. Still, it is argued, food irradiation helps destroy pathogenic germs in food—Salmonella for instance, *Clostridium botulinum* for instance. However, different types of microorganisms vary considerably in sensitivity to radiation, contrary to hea sterilization. Some spores are even more resistant to radiation than living

germs. Moreover, it can happen that within one single species highly radiation-resistant biotypes are selected out, or renewedly formed by mutation, the effect being that radiation can breed an entirely new microflora. The ramifications of this finding run into too many box canyons to comprehend instantly.

Those who promote irradiation—press releases to the contrary—are not quite prepared to abandon the nitrates, nitrites, antibiotics, reducing compounds and antioxidants, chloride, hydrosulphides, ascorbates and all the rest of modern food fabrication's claptrap. Nor are they about to abandon pre-kill injections of slaughter animals. In all cases there are synergistic actions.

Actually there is nothing very new about irradiation, except that now industry has an abundance of cheap radioactive materials developed at fantastic expense to utility customers nationwide. The foundation for the procedure was put down with the discovery of X-rays by Röntgen in 1895. Work with nuclear radiation by Curie and Rutherford added to the body of knowledge, as did Thomson's work with cathode rays in 1897. The arrival of the atomic age rounded out missing links in the technology for use of irradiation.

Soon after WWII in 1945, industrial firms and their captive scientific institutes in various nations, chiefly in the U.S., kicked open the door. The Atomic Energy Commission marched in. By 1953 a large-scale program was started by the U.S. Army.

Soldiers became uncomplaining guinea pigs. The logistics of preserved food for long patrols and field activity was perceived to offset latent danger to health. USDA joined the U.S. Army and a Canadian government-backed firm called Atomic Energy of Canada Limited, in developing basic technology. With a hotbox ready to go, all the industry now needs is approval. And the climate at FDA suggests that wholesale approval will be forthcoming. As with careless drenching of GIs with Agent Orange during the Vietnam affair, the military leaders failed to consider the consequences—or perhaps chose to ignore them.

The last statement is made advisedly. In 1966 there was a symposium on food irradiation in Karlsruhe, West Germany. Great international food agencies were invited, but those who came were mainly representatives of industry. By then the systems for irradiation were pretty well established.

Add a few words to your vocabulary again: rad, krad and mrad. A rad is a physical unit for absorbed radiation. More specifically, it is the measure for the energy absorbed by 1 gram of material irradiated with energetic rays (physically corresponding with 100 erg per gram). A krad is a kilorad, and it equals 1,000 rad. A mrad is a megarad and it equals 1 million rad.

As long as 15 years ago the state of the arts for food irradiation had already leveled off. For instance, it was known that it took 1 to 5 mrad to sterilize food. Virus annihilation required 5 to 10 mrad, and such a dose induced considerable qualitative losses in all treated foods, and led to the formation of toxic products in food.

Pasteurization of milk by ionizing radiation required between 0.1 and 1 mrad. Even at such low levels the process has a drastic effect on the quality of the food.

In the case of fruits, metabolic inhibition and increase of durability could be attained by partial inactivation of enzymes. Total inactivation of the enzymes took 5 to 100 mrad, but this level destroyed the quality of fruits and vegetables to a point of making them unmarketable. Thus the experts settled on 0.2 to 0.4 mrad for pears; 0.5 mrad for apples; 0.3 mrad for citrus fruits; and 0.4 mrad for strawberries.

Radiation loads for preventing insect attacks in stored wheat, peas, beans, flour, dried fruits—on and on—were established, as were levels that would presumably enforce birth control on spores in particular, and fungus proliferation in general. Some storage problems required truly great doses. In the case of Trichinella, a destructive dose amounted to 10 to 30 krad. Research revealed that in order to reduce Salmonella 10^7 egg powder needed 700 krad, a very powerful fix.

We will not attempt to report here the names of scientists who discovered the effects of irradiation on the contents of food. The list would be too long. But the simple facts they made a matter of record can be stated with alarming brevity.

PROTEINS

Radiation in food effects the separation of lateral chains and end groups of these molecules. The separated groups include amino acids. Considerable quantities and varieties of hydrocarbons are formed, partly volatile in nature. Included in this inventory are methyl and ethyl mercaptan, dimethyl and carbonyl sulfide, hydrogen sulfide, benzol, toluol and methane.

AMINO ACIDS

Amino acids which contain fission-able lateral chains of sulfur are tremendously sensitive to radiation. Individual amino acids in foods are disintegrated in a specific manner, according to the chemical synthesis, under the influence of irradiation. For instance, phenylalanine disintegrates to form toluol and benzol. Tyrosine does the same to form phenol and cresol. From cysteine and methionine are formed sulfides, methyl mercaptan, sulfur dioxide and hydrogen sulfide. As a consequence of disintegration caused by radiation of amino acids, great amounts of carbon dioxide are released.

FATS AND FATTY ACIDS

Fatty acids are sensitive to irradiation. The quality of oil suffers enormous changes at medium radiation doses, and even more at high doses. At medium to high doses, toxic substances are developed. Irradiation of soybean oil results in a changed iodine number, a rise in the peroxide and acid values, and destruction of tocopherol (vitamin E).

LIPIDS

Lipids are very sensitive to irradiation. Under such treatment, lipids produce breakdown products, and this—in irradiated meat—accounts for repulsive odors. What happens is this: the lipid molecules are separated by radiation through dissolution of their molecular bindings. A number of radicals are formed, and these combine with oxygen to form things like hydrogen peroxide. One researcher analyzed more than 80 volatile compounds of lipids disintegrated by irradiation. Particularly numerous were the carbohydrates, which themselves can be disintegrated into highly toxic compounds when subjected to irradiation. One researcher identified no less than 15 different alkanes (saturated hydrocarbons) and 13 alkenes (unsaturated hydrocarbons). The latter were especially olefin compounds. Also found were methyl esters, methyl acetates and acetone.

CARBOHYDRATES

Carbohydrates hoisted a warning flag all their own when examined in terms of irradiation. Disintegration under irradiation produce substances which injure cell division and probably hereditary structures. Most of these breakdown products were chromatographically determined.

NUCLEIC ACIDS

Even grade school kids know that deoxyribonucleic acid and ribonucleic acid (DNA and RNA) carry the blueprints of life. Genetic information contained in the DNA and RNA determines the basis for cell division and the life process in general. Nucleic acids are extremely sensitive to radiation, and also to irradiation products in food. Irradiated foods that offend the localities of transmission of genetic information

to protein molecules are particularly sensitive to radiolysis products formed in the cells.

ENZYMES

In order to destroy large molecular proteins with catalytical qualities outside their biological binding, high doses must be used. This is a general rule At the same time it must be remembered that, say, a respiration enzyme transmitting oxygen in potatoes is changed by 10,000 rad. Moreover, so-called unchanged or insignificantly changed enzymes in irradiated foods often develop a high activity. Thus the enzymatic decomposition of meat is considerably increased after irradiation. This is the reason offsetting steps have to be taken with meat, such as treating slaughter animals with adrenaline in order to reduce the activities of the ferments which dissolve proteins.

VITAMINS

Irradiation also destroys vitamins. The industry hopes to make an end run around this problem by adding vitamins after irradiation. Unfortunately biopotency of vitamins is affected by simply adding vitamins to irradiated food.

RADIOMIMETIC SUBSTANCES

Most of the objectives to irradiation of food pale into insignificance when compared to the radiomimetic factor. The very process of irradiating foods forms radiomimetic chemicals. These are chemicals that ape the character of radioactivity. The farm chemicals generally are radiomimetic.

In the cell, plant, animal or human, there are chromosomes which carry almost all of the information needed to direct that cell's growth, division and production of chemicals such as proteins. These chromosomes are composed of information-bearing genes. Radiomimetic chemicals (chemicals that ape the character of radiation), radiation itself, and many of the chemicals used in agriculture can injure the chromosomes either by altering the chemistry of a single gene so that the gene conveys improper information (called *point mutation)* or by actually breaking the chromosome (called *deletion).* The cell may be killed, or it may continue to live, sometimes reproducing the induced error. If it contiaues to live, its self-regulatory powers are often affected. Some types of cell damage may cause genetic misinformation that leads to uncontrolled cellular growth. The phenoxy herbicides all operate on this principle. In human beings the same general phenomenon is called cancer.

Cellular damage because of malnutrition or the invasion of toxicity can cost a farmer either part or all of his crop. The same damage in human beings can cost a nation its heritage and its future. Damage to the sperm or ova in a human being can cause malformation or mental retardation in future generations. It can also contribute to degenerative metabolic disease. Indeed, the United Nations Scientific Committee on the Effects of Atomic Radiation has noted: "It is generally accepted that there is a genetic component in much, if not all, illness." Researchers have determined that a group of radiomimetic chemicals, the epoxides, form up in foods as a consequence of the irradiation process.

#325

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THE SCIENTIFIC SYSTEM AND IRRADIATION

I have no objection to the sale of irradiated food to willing buyers—provided the buyers are not tricked into buying it (a) by false claims about its safety and/or (b) by inability to detect that irradiated food is what they are buying. In short, *I am emphatically in favor of labeling irradiated foods at the retail level as irradiated,* and I am emphatically in favor of honesty in statements issued about their safety.

From a lifetime of research in both heart disease and cancer, I know what sort of studies are required to ascertain the delayed effects and the cumulative effects on humans of biological agents such as diets, drugs, pollutants, and energy-transfers (ionizing and non-ionizing radiations). Animal studies and cell studies can provide information of only limited value about carcinogenicity, teratogenicity and mutagenicity. The kind of epidemiologic study required to find out whether or not a diet of irradiated food will increase (or possibly decrease) the frequency of cancer or genetic injuries among humans simply has not been done.

What is more, such a study is unlikely ever to be done, because it would require controlling the diets of at least 200,000 humans of various age-groups for at least 30 years, and following their health-histories for at least 50 years (preferably their full lifespans).

It is probable that we shall never know whether or not irradiated foods are safe. What we do know with certainty is that irradiation causes a host of unnatural and sometimes unidentified chemicals to be formed within the irradiated foods, and that the number, kind and permanence of these "foreign" chemical compounds depend on the food itself and on the dose of radiation.

Our ignorance about these foreign compounds makes it simply a fraud to tell the public that "we know" irradiated foods would be safe to eat. The meaning of the word "safe" is not relative. Safe means "involving no risk . . . unable to cause trouble or damage." The right of free people to buy products of unknown safety, like their right to accept hazardous jobs, is matched by their right to be free from fraud, deception and trickery in such transactions. Both rights are at issue in the labeling of irradiated foods, an issue which differs from the pollution issue because purchases and work-contracts are voluntary acts, whereas pollution is a coercive act which *forces* people to breathe, drink and eat substances which they cannot avoid.

The reason that it is dishonorable to trick people into buying irradiated foods (which they might otherwise choose not to buy), by failing to label them as irradiated and by making false safety claims, is because such behavior is a violation of the basic human right. The basic human right, upon which the U.S.A. was founded as an inspiration to all mankind, and which provides guidance to the F.D.A. and to all of us on matters of honor, cannot be stated too often: *The basic human right, from which all other genuine human rights derive, is the right of every peaceable individual to hold himself and his property free from human force and fraud, provided he helps to defend the right for all other peaceable individuals.*—*John W. Gofman, M.D., Ph.D., in FDA testimony, February 28, 1984.*

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COMMENTS ON FOOD IRRADIATION AND H.R. 696

by

CONSUMER ALERT
1024 J St. Ste 425
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presented to the

Sub-Committee, Department of Operations,
Research and Foreign Agriculture

Chairman, Hon. Berkeley Bedell

Statement prepared by
Barbara Keating-Edh, President
of CONSUMER ALERT

CONSUMER ALERT is a nationwide membership organization of consumers seeking to advance the consumer interest through advocacy of competition in the marketplace, reduced government interference in commerce and the provision of accurate information to assist consumers in making reasoned economic judgments on their own behalf. Incorporated in Washington D.C. as a 501(c)(3), tax exempt, research/education organization, CONSUMER ALERT is supported by dues from its individual members who reside in all fifty states, as well as by voluntary contributions and subscriptions to its publications. CONSUMER ALERT has no support from sources that would stand to gain financially from the promotion of food irradiation processes.

We appreciate this opportunity to comment on the overall advantages we see to the process of irradiation of food and on H.R. 696 in particular.

CONSUMER ALERT is enthusiastic in its support for this technology which we consider to be beneficial to the American public. As undoubtedly your Committee has noted, the advantages are well known and numerous. Food irradiation promises to add to the arsenal of food protection processes along with salting, smoking, drying, canning and freezing. It can eliminate the need for preservatives which is greeted with enthusiasm by many consumers. Likewise, the irradiation process can eliminate the need for fumigants on food products, such as ethylene dibromide EDB, and reduce the use of nitrite in curing certain meats,which is good news to many consumers as well.

The benefits include sterilization, pasteurization, disinfection and preservation to eliminate the microorganisms that decay food and the molds known to be carcinogenic. Trichinosis and other harmful pests can be eliminated from pork and other food products. Sprouting in potatoes and onions is delayed. The variety of foods that can benefit from the irradiation process is broad, including meat, fish, fruit vegetables, spices and grains. These are the direct and obvious advantages. Additional benefits come in the form of being able to transport fruits and vegetables when ripening can be slowed; easing of state and country restrictions set up to prevent pest infestation; and trade advatanges with foreign nations having poor refrigeration facilities.

There is little doubt consumers not only will accept this process

But will do so enthusiastically when they know that it is safe, that foods are just as nutritious and that the process has the ability to rid our food supply of unhealthy microorganisms without chemicals. Moreover, foods treated in this manner have the texture of fresh, which is radically different from fruits, vegetables, poultry and meat which has been subjected to the high temperatures required by canning.

Consumers will look favorably upon the irradiation process from the standpoint of economy, for they will have the advantage of 'fresh' without the loss of rapid spoiling. No doubt food processors will look to the advantages of energy savings, as the process can be carried out using less energy than conventional methods presently in widespread use.

That irradiation is a process, not an additive, there can be no doubt. The process which has been used successfully in the space program and studied by scientists for thirty years has granted sufficient time to ensure its safety. It has been noted that more is known of the chemistry, nutrition, toxicology and microbiology of these foods, than is known about fresh foods we cook over an open flame.

Irradiation, besides limited use in our own country now enjoys acceptance around the world from Japan to the Netherlands, from France to Africa. The World Health Organization in a 1981 document stated:

> "All the toxicological studies carried out on a large number of irradiated foods, from almost every type of food commodity, have produced no evidence of adverse effects as a result of irradiation. Radiation chemistry studies have now shown that the radiolytic products of major food components are identical...Most of these radiolytic products have also been identified in food processing...The nature and concentration of these radiolytic products indicate that there is no evidence of toxicological hazard...The technological and economic feasibility of food irradiation on an industrial scale should be established. A wider variety of foods should also be studied with respect to their suitability for processing by irradiation." 1

Though enthusiastic as an organization, about this process which promises substantial rewards and changes in the way much of our food is preserved, we are not blind to the legitimate concerns which are raised by the technology of ionizing radiation. We are aware of the need to pay particular attention to five areas including, toxicology, nutrition, microbiology, packaging and labeling.

We are aware that significant assessment and investigation has taken place with regard to the general toxicology and that it has been found that some new substances have been produced called radiolytic products. We are confident that testing to date has shown these substances to be no different than those formed in other food processing methods and that they are not known to cause cancer, interfere with reproduction or cause genetic changes in offspring.

We are aware too that the nutrition value of food needs to be protected during processing. Most methods in use affect nutrition to some degree. It would seem that irradiation methods appear to be at least as good as other processes. Higher doses of exposure, obviously show camparable reductions in nutrition levels. It would seem that good sense should prevail, with exposure levels set to achieve the task without resorting to overkill and interfering with nutrition or texture. We recognize that not all foods are suitable candidates for irradiation processing.

It is obvious that there are limitations to the effectiveness of any food process and irradiation is no exception. All foods can become contaminated with microorganisms after the fact. It is important to ensure that the irradiation process is consistant and reliable.

Since some food can be packaged before being irradiated, a remarkable advantage exists toward increased efficiency and sanitation. Testing will still be needed to ensure that packages themselves are not adversely affected causing hazards to develop.

Appropriate labeling is imporant to many consumers though we recognize the fact that millions of shoppers don't read labels. It is important that labeling serve to inform, not to frighten. We suggest adequate and appropriate information would be contained in the words, "sterilized by ionizing radiation, or sterilized by ionizing energy in place of chemical preservatives or fumigants".

It is appropriate that testing continue regarding the effects of high levels of radiation exposure. Likewise we would urge continued review of the critical examinations which have taken place on unique radiolytic products, URP's though we are confident that such tests have proven that these pose no health risk whatsoever to the public. The Select Committee on Health Aspects of Irradiated Beef, organized by

The Federation of American Societies for Experimental Biology, concluded in reviewing these tests that:

> "There were no grounds to suspect that the radiolytic compounds evaluated in this report would constitute any hazard to health to persons consuming reasonable quantities of beef irradiated in the described manner." 2

CONSUMER ALERT supports the stated goals of H.R. 696, that is the coordinated development and commercialization of food irradiation. If a Joint Commission is established we would urge that its mandate clearly be to facilitate the development of this technology. We are concerned that many committees thus established by Congress often work at cross purposes with their stated goals and become snags which wrap the competitive private sector in bureaucratic red tape, preventing it from moving forward at the pace prompted by consumer demand, scientific findings and technological development. We would rather drop the word "Control" from the title of the Act.

Though we agree national uniformity of regulation has certain advantages, federal uniformity lacking flexibility has the potential of restricting innovation and variations in processing. We would urge that regulations be set to allow for needed flexibility. Sec. 2B(4)

We are confident that industry advertising is a good education tool, often motivated by competition. Further public understanding can be advanced by consumer columnists, and printed matter devoted to consumer education. The best role government can play in ensuring public understanding and confidence in the irradiation process, is by resisting the political temptation to fall prey to the delay tactics which will be attempted by those are anti-technology by profession. Public confidence will be assured by a straightforward attitude and coordinated approach on the part of government regulatory agencies. It is important that government resist the detractors of this technology, who, there is little doubt will raise concerns about "public exposure to radioactive food stuffs", doubts about "cancer causing radiolytic substances" and the "risk of transporting radioactive materials or worker exposure." Government must recognize this resistance from its source. It will be coming from a few vocal activists who are not willing to recognize radiation in any form as a part of our lives nor willing to admit that man has the ability to use it to his advantage for peaceful purposes. Their opposition is

reminiscent of those who objected to the introduction of electricity to the City of New York at the turn of the century, so convinced were they that this fearsome technology was suitable only for electrocutions and could not be harnessed to man's benefit. Sec. 2 (3)

We wholeheartedly endorse revising the Federal Food, Drug and Cosmetic Act to recognize irradiation as a process not a food additive.

In light of the size of the national deficit and the need to drastically reduce the cost of government, we express concern that H.R. 696 would advance expenditures on the part of the federal government, and we urge those who consider passage of this Bill to seek innovations which may allow for less or no spending, by seeking the financing for this Joint Operating Commission for Food Irradiation in the Department of Agriculture, from already existing sources within the Department.

In conclusion, we restate our support for this important technology, for it could have many benefits for U.S. consumers by increasing the variety of techniques that can be used to provide a safe, wholesome, convenient food supply. Extensive scientific testing has shown that proper use of food irradiation does not present a health hazard. All of the evidence indicates that consumers have nothing to fear from irradiated foods, but instead can look forward to a greater variety of high-quality food products if this process comes into widespread use.3.

- END-

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OSPIRG A BALANCE FOR THE PUBLIC INTEREST
OREGON STUDENT PUBLIC INTEREST RESEARCH GROUP

TESTIMONY OF

SHARON LEVY

PROJECT LEADER, FOOD IRRADIATION RESEARCH PROJECT
OREGON STATE PUBLIC INTEREST RESEARCH GROUP

ON H.R. 696

SUBMITTED TO THE SUBCOMMITTEE ON DEPARTMENT
OPERATIONS, RESEARCH, AND FOREIGN AGRICULTURE
NOVEMBER 18, 1985

Chairman Bedell and Members of the Committee:

I am project leader of OSPIRG's food irradiation research project. OSPIRG is a statewide consumer and environmental protection organization with over 25,000 members.

We at OSPIRG wish to express our concern over the proposed bill, H.R. 696. The establishment of government policy promoting development of food irradiation facilities, promoting a campaign for public acceptance of food irradiation, and eliminating all requirements for labeling of irradiated food, is completely unwarranted at a time when the process has not been proven safe. Irradiation alters the chemistry of food, causing the formation of unique radiolytic products (URPs), compounds which are not normally found in food. The chemical structures and health effects of URPs are unknown. Irradiated foods should therefore be subjected to the same thorough toxicologic testing required of any new food additive. If and when irradiated foods are sold, they must be labeled as such.

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Several studies have demonstrated adverse effects due to a diet of irradiated food:

- A study from the National Institute of Nutrition of the Indian Council on Medical Research, showed that children fed irradiated wheat developed polyploid and otherwise abnormal white blood cells, which persisted in the circulation for 16-20 weeks after withdrawal of irradiated wheat. In children fed unirradiated wheat, no polyploid or abnormal cells were seen.[1]

  A second study from the same Institute reported increased polyploid bone marrow cells in rats fed irradiated wheat.[2]

- Studies on rats given irradiated food showed damage to the kidneys and testes. Increased severity of damage in both conditions correlated with increased dose of irradiation of the food.[3,4]

- USDA sponsored studies, carried out by Raltech Scientific, showed increased testicular tumors, increased mortality, and kidney disease in mice fed irradiated food. Raltech also did a study on flies given irradiated chicken, which showed increased mortality of offspring.[5]

- Some studies suggest that irradiation causes increased

production of carcinogenic aflatoxins in grains.[6,7]

Several major studies which seemed to support safety of irradiated fruit, vegetables, and fish, have been discredited. These studies were conducted by Industrial Biotest Laboratories. Three IBT executives were recently convicted of falsifying test results in studies on a variety of chemicals.[5,7]

In light of these facts, it is difficult to understand the FDA's proposal that no toxicologic testing be required for foods exposed to less than 100 kilorads. FDA is presuming safety of such foods based solely on the estimated amounts of URPs which would be formed in the food. The 1980 Final Report of FDA's Irradiated Food Committee recommended this step, but in their determination of safety they did not consider any of the available data on the toxic effects of irradiated food. The character of URPs is unknown, and variable in different types of food. It can hardly be prudent to declare these compounds harmless based only on their concentrations in food, when their possible toxic effects and potencies are unknown. Many toxins are known to exert their effects even at low doses.

Dr. John Gofman, an expert on radiation and human health, has stated that

> "....the kind of epidemiologic study required to find out whether or not a diet of irradiated food will increase (or possibly decrease) the frequency of cancer or genetic injuries among humans simply has not been done..... What is more, such

> a study is unlikely ever to be done because it would require controlling the diets of at least 200,000 humans of various age-groups for at least 30 years, and following their health-histories for at least 50 years (preferably their full lifespans)." 8

It is indeed unlikely that such a study will ever be done. Aside from the immense practical difficulties, there are moral implications as well. Human experimentation is ethically unacceptable to the scientific community, and to society as a whole. Yet under the provisions of H.R. 696 and the proposed FDA regulations, the entire U.S. population would become the unwitting subjects of an uncontrolled experiment in the effects of irradiated food.

We urge the FDA to reconsider its proposals permitting the sale of untested irradiated foods. Certainly Congress should not add to the problem by passing a bill promoting the clandestine production and sale of food of questionable safety. However, if irradiation of food is permitted, it is essential that the food be labeled clearly and that consumers be given the opportunity to make an informed choice.

We strongly agree with Dr. Gofman that to tell people that irradiated food is known to be safe is a lie; to trick people into buying irradiated foods by failing to label them is a fraud. The idea that irradiated foods should not be labeled lest the public refuse to buy them is totally unacceptable as a basis for legislation. When Congress acts on the issue of food irradiation, it must be with the recognition that irradiated food may present a health hazard, and that citizens have the right to make a free choice regarding their own exposure to avoidable hazards.

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UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

19 NOV 1985

Mr Tim Galvin
Committee on Agriculture
U.S.House of Representatives
1301 Longworth Building
Washington DC 20515

Dear Mr Galvin,

During the hearings on Congressman Morrison's irradiated foods bill, Congressman Bedell expressed interest in regulations in the United Kingdom. Congressman Bedell may be interested in the attached paper describing the U.K. position on this subject.

Yours truly,

Philip F. Lewis
Chairman,
Interagency Committee on
Food Irradiatiation
U.S. Department of Commerce

Attachment

CONSTRAINTS ON THE INTRODUCTION OF IRRADIATED FOOD INTO THE UNITED KINGDOM

W R BRADFORD

(A presentation to the IAEA Task Force Meeting on Trade Promotion of Irradiated Food, Vienna, October 1985)

Introduction

The United Kingdom was among the very first nations to recognise the potential of irradiation as a means of food preservation, and a considerable amount of pioneering work was carried out in the 1950s and 1960s at a number of locations in Great Britain; a dedicated centre for such research was even set up by the United Kingdom Atomic Energy Authority at Wantage near Harwell.

Once the practicability of the process had been established, the then Ministry of Health instituted a review of the medical and scientific information about the effect of irradiation upon food, including any changes in its nutritive value, and the possible hazards to man that might thereby arise. The Working Party appointed to carry out this review was further asked to report on the need or otherwise for official control, and if control were recommended to indicate the principles which should govern it.

The report of the Working Party was published in 1964 (1) and was a substantial and remarkably far-sighted review. Virtually every aspect of food irradiation with which we are familiar today (with the exception of the labelling issue) was identified and given due consideration. The Working Party listed certain hazards to health which could possibly arise from the consumption of irradiated food, but concluded that such hazards could be reduced to negligible proportions if food were irradiated under controlled conditions. For this reason, it was recommended that statutory control over the irradiation of food was desirable and that control should take the form of prohibition from which exemption could be obtained under specified conditions.

The Government of the day duly acted on these recommendations and made appropriate regulations under the Food and Drugs Act 1955 (2) which with minor amendments are still in force today. The existence of these regulations and their restrictiveness is often cited as the main if not the only reason for there being no foodstuffs yet cleared for sale within the United Kingdom at the present time, but it should be appreciated that they are little different in substance from legislation in force in many other countries of the world wherein specific clearances for the irradiation of food commodities have been granted.

Certainly the regulations represent a significant constraint on the introduction of irradiated food into the United Kingdom, but by no means an over-riding one. If one examines all the possible reasons why no applications for exemption from prohibition have progressed to completion, then other constraints begin to emerge which together constitute a more formidable barrier - or if not a barrier, at least an explanation why a process with such initial promise has not so far been adopted by the food industry in the United Kingdom.

However, the first constraint in the list which follows stems directly from imposition of the controlling legislation.

Evidence of Wholesomeness

The constraint on introduction of irradiated food which was particularly important at the time that the Working Party submitted its report, (and which remains under present United Kingdom legislation), was the need for evidence of wholesomeness to be provided in support of any application for exemption from the regulations. A full range of tests was required including investigations for a possible dimunition in nutritional value and for the possible presence of toxic substances in general and of carcinogens and radioactive substances in particular, as well as evidence as to the nature and results of microbiological tests on the irradiated food before and after storage under stated conditions.

Such testing was clearly beyond the in-house capability of all but the largest companies, and the number of firms able to undertake such work under contract was small. Similarly, the facilities capable of irradiating experimental batches of food for testing were few in number and not always suited to the irradiation of food under conditions approximating to a commercial plant. Certainly no potential user was going to install a commercial facility before an exemption could be obtained.

This situation was not peculiar to the United Kingdom of course but was common with any country where the use of irradiation was contemplated. It thus formed an ideal opportunity for collaborative research to reduce costs and avoid duplication of effort, and happily such collaboration was forthcoming in the guise of the International Project in the field of Food Irradiation (IFIP) hosted by the institute of food research at Karlsrühe from 1970. The United Kingdom was associated with the Project from its inception, providing financial support and members of both Management and Scientific Programme Committees. The successful completion of IFIP's programme culminating in the 1980 Joint FAO/IAEA/WHO Expert Committee on Food Irradiation (JECFI) is too well known to need repetition.

If the recommendations of this JECFI(3) were to be accepted and acted upon in the United Kingdom, it would remove the onus of proof of wholesomeness from the prospective user and thus significantly enhance the attractiveness of the process to the food industry. Additional impetus would be given to the introduction of irradiated food into the United Kingdom if at the same time other countries were seen to be moving towards acceptance of the 1980 JECFI recommendations, and internationasl trade would be immeasurably facilitated if the Codex General Standard for Irradiated Foods and associated Code of Practice (4) were to be generally adopted.

Technological Need

The next constraint comprises a set of circumstances more specific to the United Kingdom. The UK is a relatively small and

compact country with temperate climate and with excellent communications; power supplies are abundant and not excessively expensive. The food production, processing and distribution industries are well developed and there are adequate supplies of home produced or imported fresh food throughout the year. There are no major public health problems associated with food-borne disease.

These factors combine to lessen the need for food preservation compared with many less fortunate nations, and where preservation of fresh food does prove necessary, the availability of a range of generally accepted techniques (e.g. heat treatment, freezing, canning and the use of chemicals) has tended to pre-empt irradiation from serious consideration; nor has there been, up to now at least, a pressing demand for irradiated food to be imported into the UK from overseas.

These various circumstances are mostly economic or socio-economic in nature and together constitute a significant constraint - namely that the consumer is unlikely to purchase irradiated food it it costs more (or even the same as) the unirradiated equivalent of outwardly indistinguishable quality. Nevertheless the situation is not wholly immutable and changes are occurring or have occurred in recent years in such a way as to make irradiation processing more attractive than hitherto.

For example, the rise in world oil prices has resulted in a widespread increase in distribution costs, so that the economic advantage of transporting larger batches of food less frequently is becoming more significant. The effect on energy costs generally is making heat treatment and refrigeration relatively more expensive. Another trend is the desire to move away from the use of chemical preservatives (including fumigants and sprout inhibitors) which are known to be associated with potential health risks either to the consumer or to the operators who apply them. There is in the UK a growing and largely unfulfilled market for tropical and sub-tropical fruits and vegetables which cannot at present be imported by sea because the maturation time after harvest is too short. Delay in ripening induced by irradiation or a combination treatment could overcome this

Another changing circumstance is the incidence of microbial food poisoning in the UK which is reported to have doubled over the past 10 years and shows no sign of having reached a peak. The cost to the community is considerable and should be set against the cost of irradiation treatment of high risk foods such as frozen poultry.

Finally a change in eating habits towards increased consumption of pre-packaged "convenience" foods could give rise to a new and particularly appropriate application of irradiation to ensure the hygienic quality and prolonged shelf life of such products. In summary therefore, the technological need for irradiation is probably greater than ever before, and requires only a small impetus to bring it to the surface.

Availability of Irradiation Facilities

Clearly the availability of suitable irradiation facilities is an essential prerequisite for the introduction of irradiated food into the UK, unless such food is to be wholly imported. Unlike many other countries, the UK has no commercial or pilot scale plant or even experimental facilities dedicated to food irradiation and has had none since the closure of the Wantage laboratories nearly 20 years ago. Several commercial irradiation facilities are however in operation for treatment of medical and other ethical products, as well as laboratory animal diets, plastics, etc, and there is ample expertise available in the construction and operation of such facilities using both isotope and machine sources. Some of the existing facilities no doubt have excess capacity which could be used for irradiation of pre-packaged foodstuffs should the demand arise; meanwhile the UK food industry is sufficiently large and well organised to undertake the construction of new custom-built facilities once economic feasibility has been established and once the other constraints on the introduction of the process have been removed. Lack of suitable facilities is therefore not considered to be an important constraint, at least in the long term.

Public Acceptability

Uncertainty over the extent to which there will be opposition

to the introduction of irradiated food into the UK has been and still is a constraint. The question is directly related to the labelling issue and less directly with issues such as the ability to detect that a food has been irradiated and the degree of control which can be exercised over trade in irradiated food.

So far, much of the publicity given to irradiated food in the media has tended to over-emphasize and sensationalise the potential benefits of the process in a way that is not calculated to inspire confidence in the mind of a thoughtful layman. Despite this, there has been no public outcry against the idea of food being subjected to irradiation, so there are grounds for hope that the British public if not actively supportive is at least keeping an open mind on the subject. More recently, opponents have adopted the tactic of highlighting the negative aspects of food irradiation in such a way as to cast doubts on the overall safety of the process and the benefits to be derived from it. It is difficult for those in favour to counter these arguments convincingly, for example within the confines of a short radio or television discussion.

Given that there will probably always be a sizeable minority of people who will prefer not to consume food which has been irradiated, a requirement to label irradiated food would probably assist in its introduction into countries such as the UK, rather than the reverse. Then as the hidden advantages of irradiated food become more widely appreciated, so would the market fraction secured by irradiated food increase.

A related topic is the question of the exercise of proper control over the way in which irradiation is carried out. There has long been a tradition in the UK that the food industry should be allowed freedom to regulate its own affairs within a broad frame-work of legislation designed to protect the consumer. This system has worked well and it is only latterly that membership of the European Community and participation in the work of the Codex has resulted in the introduction or at least the prospect of more specific restrictions and guidelines. Even so, the Codex General Standard on Irradiated Food itself recog-

nises the importance of the principle of "Good Manufacturing Practice" in establishing the parameters for irradiation, while at the same time making provision for supervision of irradiation facilities by national authorities, and specifying that documentation should accompany batches of irradiated food up to the point of retail sale.

It is considered that such provisions are a necessary adjunct to the process of achieving public acceptability of food irradiation within the UK, not only by those who are potential consumers but also by those who wish to avoid irradiated food. It is also very desirable that all countries which permit food to be irradiated now or in the future should comply with the recommendations of the 1980 JECFI and the requirements of the Codex Standard in respect of control and documentation. Only then would it be possible to provide reasonable assurance to consumers in the UK that irradiated food could not unknowingly enter the country. Lack of the ability to give this reassurance at present contributes to the constraint represented by uncertainty about public acceptability.

Legislation

Existing UK legislation has been described in the Introduction, and takes the form of prohibition (with minor exceptions) coupled with provision for exemptions to be granted on application. Following publication of the report of the 1980 JECFI, the Health and Agriculture Ministers decided to re-form the Advisory Committee on the Irradiation of Food which had been first established at the time that the regulations were made in 1967. The new Committee was given the additional task of considering novel foods and is therefore known as the Advisory Committee on Irradiated and Novel Foods (ACINF). The Committee's remit in respect of irradiated food was to "advise the Ministers on any matters relating to the irradiation of food" and in particular to review the relevant scientific data bearing on the safety and wholesomeness of irradiated food.

The Committee first met in May 1982 and originally planned to complete its work and submit a report to Ministers during 1984. This target proved impossible to achieve, but the Committee's report is now understood to be virtually complete and is expected to be submitted within the next few weeks. It is then expected that the report will be made public, probably early in 1986.

There has already been much speculation about the contents of the Committee's report, and several media articles have predicted that it will prove to be generally favourable towards food irradiation. If this proves to be the case, the Government has then to decide whether or not to amend existing legislation in the light of the report and its recommendations, also taking into account the views and opinions expressed by interested parties such as food producers, processors and importers, consumer groups, public health authorities and so on. Another factor which may influence the Government will be the possibility of action to harmonise attitudes to food irradiation within the European Community.

Conclusion

A number of constraints on the introduction or irradiated food into the United Kingdom have been identified. Together they have resulted in the situation that no food for sale to the public has yet been treated by irradiation at the time of preparation of this paper. No one of the constraints is however considered to be absolute, and there are hopeful signs that the magnitude of many of them may be diminished in the foreseable future. The next twelve months may therefore see a marked change in the irradiation scene within the UK.

Note

The opinions expressed in this paper are the author's alone and do not represent official UK policy.

References

(1) Report of the Working Party on Irradiation of Food. HMSO 1964

(2) The Food (Control of Irradiation) Regulations 1967 SI 1967 No 385, as amended by The Food (Control of Irradiation) (Amendment) Regulations 1972 SI 1972 No 205

(3) Wholesomeness of Irradiated Food. Technical Report Series No 659. WHO 1981

(4) Codex General Standard for Irradiated Foods, and Recommended International Code of Practice for the Operation of Radiation Facilities used for the Treatment of Foods. CAC/Vol XV - Ed 1

22 November 1995

The Hon. Berkley Bedell, Chair
Subcommittee on Department Operations, Research, and Foreign Agriculture
Committee on Agriculture

and

The Hon. E (Kika) de la Garza, Chair
Committee on Agriculture
U.S. House of Representatives
Washington, DC 20515

Dear Representatives Bedell and De la Garza:

This letter is submitted as testimony for hearings scheduled by the Subcommittee on Department Operations, Research, and Foreign Agriculture, for Monday, November 18, 1985.

The Consumers Cooperative of Berkeley, Inc., firmly opposes HR 696 and S.288. We have notified our 128,000 members of the hearings and of our concern regarding this bill. We think it is a dangerous bill for a number of reasons:

it would mandate and finance research and development of irradiation of food by the Federal government-- surely inappropriate given the current Federal deficit;

undertaking a Federal promotional campaign would be yet another waste of taxpayer money;

production of gamma emitting sources for foreign use is clearly dangerous and unwarranted;

labeling of irradiated food should be made mandatory by the Federal government, utilizing the internationally known radiation symbol, both at the retail and the wholesale level, so that consumers can continue to exercise their rights to know what they are eating; this legislation would forbid labelling;

and finally, the establishment of a commission is not only a waste of taxpayer money, it is clearly unnecessary and not the proper use of government.

Our opposition was made formal by a vote of the Board of Directors of the Consumers Cooperative of Berkeley, Inc., at its meeting of June 6, 1985, adopting the following resolutions on the issue of irradiation of food:

CONSUMERS COOPERATIVE OF BERKELEY, INC. 1600 Central Ave., P.O. Box 4030, Richmond, CA 94804-0006
• • • •

Resolution I:

Whereas food irradiation is a technology with consequences to food that have not been completely analysed and evaluated at the present time; and

Whereas serious questions have been raised on food irradiation that need further specific research, public scrutiny, and examination of all issues raised; and

Whereas the use of radioactive sources in food irradiation facilities would increase the chances of accidental exposures to radiation during transportation and use, and add to the unsolved problem of safe disposal of radioactive wastes; now, therefore, be it

RESOLVED that the Consumers Cooperative of Berkeley, Inc., shall demand that the public be protected from the potentially dangerous substances that are created due to the treatment of foodstuffs by irradiation until sufficient and conclusive, unbiased research and testing have been conducted to establish the safety OR the peril of irradiated foods, and be it further

RESOLVED that the Consumers Coooperative of Berkeley, Inc., shall oppose any legislation, federal or otherwise, that would prematurely seek to implement and/or further the irradiation of foods prior to full and sufficient evidence brought forth by testimony and public hearings that all the issues of safety involving food irradiation (including environmental, health, and economic consequences) have been concluded, with reports of these available to the public.

Resolution II:

Whereas currently food irradiation is classified as a food additive and as such is subject to specific scrutiny and regulation by the Food and Drug Administration, and

Whereas there is proposed Federal legislation (HR 696 and 5288) that would remove food irradiation from the category of "food additive" to a "food process" which would diminish many of the required Food and Drug Administration regulations regarding irradiation of food, and

Whereas this reclassification would permit the irradiation of foods and sale of these foods to the public without being labeled in any way to indicate that they have been treated by irradiation, and

Whereas it is critical that consumers' rights be fully informed and recognized and protected, now, therefore, be it

RESOLVED that this organization go on record as demanding that any and all food, or parts of food, that have been irradiated shall be clearly labeled as such when offered for sale at the wholesale and retail levels with a readily identifiable and visible image that represents irradiation and an accompanying explanatory statement.

We urge the members of the Committee to defeat this dangerous piece of legislation. This organization has conducted two educational campaigns on this issue during the past year and a half. As a result, thousands of letters have been addressed to a number of members of Congress as well as to the Food and Drug Administration. We intend to use whatever means we have at our disposal to oppose this current piece of legislation, both with our own membership and with our fellow cooperators across this country.

Thank you for your attention in this matter.

Sincerely yours,

Bruce Miller
President,
Board of Directors

BAM/NS/d
c.c. Lynn MacDonald
Nancy Snow
Board Members

0136N

November 18, 1985

The Chairman
The Subcommittee on Operations, Research, and Foreign Agriculture
The Committee on Agriculture
The U.S. House of Representatives
Washington, D.C. 205

Dear Mr. Chairman,

Thank you for the opportunity to submit this testimony to your Sub-Committee. The subject is that most important issue which is often referred to by that overly broad, often misleading terminology "food radiation". This is a food processing technique which will save lives, will reduce illness, will reduce food losses, and will generally, significantly improve the quality of life for all of mankind! Those who contend otherwise would deliberately mislead their audience!

Every recognized, legitimate, scientifically based agency and organization involved in radiation science, food science, food production and distribution, and public health has published an opinion on the subject to the effect that for consumers of foods processed with this very specific electromagnetic energy of approximately one picometer wavelength, in accordance with FDA's proposed regulations, there will be no increase in risk!

Over the last forty + years, many more than a thousand authoritative research papers, books, reviews, etc., on various aspects of this subject have appeared in publications respected by the world of scientific bodies and personages. (I have attached listings of many of these publications.) There is no lack of knowledge on this subject within the world's body of qualified, appropriate scientific organizations and researchers, and they have long since published without qualification that there will be no increase in risk for the consumer of foods processed with this technology as FDA and others have proposed that it be done!

In spite of all of these authoritative publications, and in spite of the respected scientific community's conscensus concerning safety of these foods, in recent months there have appeared in a few specialized (not scientifically accepted) publications, and in some newspapers and magazines, a few articles generally written (it would apear) to be attractive to those who distrust the "establishment". Often their authors' objective would appear to be to tear down many of the world's technologically based improvements in mankind's "quality of life". Unfortunately, you have been subjected to misleading testimony from such as those authors.

In this testimony I will focus upon several of the criticisms of this technology made by such authors, and by some who testified at this hearing. I will also focus upon some of the positive aspects of use of this technology, and upon lending some perspective in the matter. Upon your request, I will produce for you recognized, authoritative sources to substantiate what is written herein.

Those who author such misleading articles, or who give false or misleading testimony on this subject often quote references which turn the scientific community's self-disciplining practices against them. In some cases they will reference irrelevant studies, or studies with a greatly different focus. Thus, such authors or testifiers who do this mislead an uninformed audience!

In specific explanation of the preceding statement, accepted practice in good scientific work involves the publication of reports on studies, experiments, investigations, etc., in the most prestigious, recognized, journals, etc., appropriate for that particular subject, which they can get to publish the report. The authors will submit their "papers" for review, often to a number of publications, serially in order of prominence, and the better publications journals, etc., will screen the papers, using recognized authorities in the field before acceptance or rejection. Sometimes, at symposia, all papers given will be published in "Proceedings" of that symposium, without any screening.

Often, and especially when the reporting is in conflict with accepted beliefs, scientific publications are followed by attempts to verify the accuracy of the published work by having several other investigations try to duplicate the experiments, studies, etc. Sometimes, a peer group will instead investigate the published experiment or study, itself, to determine the competency of the author(s), the circumstances of the work, the adequacy of the facilities and equipment, the correctness of the procedures used, etc. On occasion, as a result of these investigations or attempts at duplication, the initial work is found to be flawed, to be erroneous, to fail to report contributing factors, to have involved unacceptable procedures and practices, etc.

In those cases in which the flawed or incorrect work is discovered, those doing the investigation or failing to be able to duplicate the work will publish their conclusions and the initial work would be partially or completely dicredited. Failure of any author who would reference scientific work but who would not also describe authoritative, well known, challenges or discrediting publications, is guilty of literary dishonesty, as far as the scientific community is concerned. In the scientific community, such dishonest actions result in respected journals refusing to publish any additional work by that/those authors. Unfortunately, your sub-committee and other sub-committees have been given such incomplete/dishonest references on this subject! (i.e. The reportings on deaths from consuming "irradiated" foods).

In the field of "food irradiation" with electromagnetic energy at picometer wavelengths, at "doses" to be permitted by FDA, published studies concluding that foods so processed would be unsafe or would not be wholesome have never survived scrutiny by recognized authorities in the field! All of the testimony you have been given making such claims for unsafe or unwholesome foods based upon reportings in recognized scientific publications has been given without you also being told that the work was subsequently discredited by recognized scientists, committees, or organizations!

It is the contention of those who publish and testify against "food irradiation" that more study is needed. In truth, there have already been more authoritative scientific studies of this picometer wavelength radiation's effects on foods and other materials than there has been on any other food processing technology! It is now becoming apparent that it is even possible to conclude that from a food safety and wholesomeness point of view, this is the best of all of the energy-employing processes to which foods are subjected.

Because there has been more study on radiation effects than there has been on all of the other "accepted" food procesing techniques put together, food scientists know far more about the effects on foods processed with Picowaves© than they do about the effects from any other processing technique. Some of these scientists are concerned because they don't know as much about "accepted" or "natural" processings, and they thus can't say with certainty that some of mankind's problems are not being caused by some of these accepted practices.

It is now becoming clear that while food scientists feel very comfortable about the safety of foods processed with Picowaves, they are no longer so confident about those processes in long term use about which they don't know so much, and thus "Generally Recognized as Safe" is no longer giving such comfort as to safety. Many in the scientific community want to subject these "accepted" practices to the same very deep scrutiny as Picowave processing has been subjected.

Every respected, recognized, authoritative scientific body in the free world which has engaged qualified experts to examine the safety or wholesomeness aspects of use of this technology on foods has concluded that there is no reason to believe that there will be any increase in risk to the public from its use on foods as proposed by FDA!

Against this well publicized world body of supporting knowledge and every appropriate respected agency's concensus that there is no question of safety or wholesomeness, it is essentially preposterous, very possibly contemptuous, and at least insulting that any testimony, substantiated by incomplete, unethically employed references, be given to a Committee of Congress!

These same authors who give such negative testimony also frequently make references to "unique" radiolytic products. As the FDA and many other have already pointed out after years of scientific investigation, there have never been discovered any "unique" radiolytic products in foods processed with Picowaves, if by "unique" is meant that there are produced chemical species not already in our diets whether from natural sources or from other processing!

Indeed, there are minute quantitiesf ochanges in chemical forms to result from "food irradiation"; however, to give true perspective, it should have been pointed out to you that this process, for disinfestation, will affect only approximately one molecule in twenty million, whereas heating will affect every molecule in the food. It is impossible to apply any energy form, or any active chemical form to foods without affecting the molecular forms in the foods. Sun drying and curing, baking, broiling, boiling, ultraviolet processing or holding, microwave "cooking", freezing, drying, aging, ripening, mixing of ingredients, etc., all cause molecular changes in foods, and todate, after extensive examination, no chemical form has been found in "irradiated" foods which is not already in the air, food and/or water mankind is routinely ingesting!

"Food irradiation" as the FDA has proposed - at 100 kilorads or less - is depositing in the foods an energy equivalent of less than one half of a btu, which equates to less than the energy required to raise one pound of matter one half degree in temperature - an extremely small amount of energy applied to the foods when compared with all other food processing techniques. Raising the temperature of foods to pasteurizing levels is putting more than two hundred times as much energy into the foods, and baking, broiling, etc., at higher temperatures is putting even more energy into the foods. Sun drying and curing is putting thousands of times more energy into the foods than is Picowave processing. There ae many more molecular changes in foods subjected to these other processes than there are in foods subjected to Picowave processing!

From a public health point of view, use of "Picowave"® processing of fruits and vegetables means reduced need for the public to ingest carcinogens, while enabling the Agricultural community to get even better control over insect transportation and quarantining. Routine use of "Picowave"® processing on pork means reduced chance of illness and death from trichinosis. Routine use of "Picowaves"® on poultry, raw milk and raw milk products (for example) would immediately reduce illness and/or deaths from food-borne disease/illness-causing microorganisms such as salmonellae, coliforms, listeria and campylobacter. If efforts to further delay use of this technology are successful, people will become ill, and some will die, and all of it will be needlessly! The motivation of the negative testifiers who would delay or prevent use of this technology cannot be protection of, or improvements in, public health!

From an environmental protection point of view, if this "Picowave" processing of foods were routinely used instead of ethylene dibromide, methyl bromide etc., for disinfestation purposes, there would be significant reductions in chemical releases to the earth, to the atmosphere and to the hydrosphere. Therefore, the motivation of the negative testifiers cannot be protection of environmental health.

Since machines will most often produce this "Picowave" energy (there aren't large enough supplies of radioisotopes, and new machines employing new principles for generating Picowaves will do a better job), there is no need for transporting radioactive materials into or through areas where they would constitute unacceptable hazards. Finally on this issue, there are never going to be any "nuclear wastes" produced by these "machines". Thus, the motivation of these negative testifiers cannot honestly be based upon safeguarding the public from nuclear or radiation hazards.

You have been given testimony concerning destruction of vitamins and nutritional characteristics of foods by use of this "food irradiation". Again, these authors and spokespeople are failing to tell the whole story. It is true that there is reduction of some of the vitamins, (or some change in their chemical form) as a result of "food irradiation", but it is also true that there is much less change than the effects of accepted practices such as letting fruit juice be exposed to light, subjecting foods to sun drying and curing, cooking, pasteurizing, aging (of the foods), mixing with the other foods and vitamins, etc. Among others, the center for Food Safety and Applied Nutrition, FDA, has examined large amounts of data and concluded that in terms of the human dietary needs, and in perspective with the realities of alternative practices, there is no significant reduction in these essential vitamins, minerals, etc. Again, the negative testifiers have withheld well known information in their testimony. It must be concluded that honest concern for the pubic's nutrition cannot be a motivation of those who testify against the ue of Picowaves® in the processing of foods.

There are those who contend that the food will be degraded in quality by use of this technology. They quote references which are reportings of improperly conducted work, and/or are reportings of attempts to find out the doses necessary to make fresh fruits and vegetables last for months in ambient storage conditions by subjecting the foods to medium-to-high doses "food irradiation" (an effort which was unsuccessful). These same persons fail to point out that a few days extension, even under improper conditions, was often experienced and reported at the same time, when the foods were given lower doses. Like any other technology, "Picowave" processing must be done correctly to avoid degradation (softening, flavor change, etc.).

Investigations into claims for food quality degradation resulting from Picowave processing of foods degradations have always uncovered improper handling and processing techniques. From the results of recent work with proper controls and under proper conditions, using lower doses, and achieving excellent results, it must be concluded that improper conditions was the cause of the degradation, not the "Picowave"® processing. Major food firm scientists working with us, and we working on our own, have processed every significantly, commercially attractive food which could conceivably profit from use of this technology. We have always been able to find a specific set of conditions for successfully, beneficially processing foods with "Picowaves"® without degradation of quality.

We have extensively investigated the reportings of flavor change or softening, etc., reported to result from this Picowave® processing, and in those instances where it was possible to find them (some of the work was done more than fifteen years ago), we have always uncovered strong testimony from participants in the work that temperature control or handling, etc., was faulty, injurious or non-existent. For essentially all fresh foods, there is every reason to believe that good processing techniques will result in very attractive foods.

The negative testifiers have often quoted or used such "experts" as Dr. John Gofman in their efforts to delay or stop use of this technology. In case of Johnson vs. United States, Judge Patrick F. Kelley of the U.S. District Court (Kansas) in a 150 page written decision following 42 days of testimony by 53 witnesses, 5400 pages of trial transcripts and 10 months of study, concluded that (among many other uncomplimentary observations on Gofman):

> "This court does find that Dr. Gofman's dramatic conflict with all of the world's experts creates a bias in him which destroys his credibility as an objective expert witness in radiation cases. His obsession blinds his objectivity".

Perhaps Judge Kelly has summarized the best explanation of the motivation of those who have submitted testimony against "food irradiation". Even though that might explain the motivation, it does not excuse or justify the tactics and doesn't correct the damage done to the environment or human life by denying/ delaying the use of this technology!

Again, thank you for this opportunity to submit this testimony to your important Sub-committee hearings. If I can be of further assistance to you, please call upon me.

Sincerely,

Niel E. Nielson, President
Emergent Technologies, Inc.
P.O. Drawer 3218
San Jose, California 95156

TESTIMONY OF CONSUMERS UNITED FOR FOOD SAFETY (CUFFs)
Before
THE HOUSE AGRICULTURE SUBCOMMITTEE ON DEPARTMENT OPERATIONS,
RESEARCH, AND FOREIGN AGRICULTURE NOVEMBER 18, 1985.

FOOD IRRADIATION and H.R. 696

Contents of Testimony

1. Organizational support for labeling and further research on food irradiation.
2. Comments on the procedures FDA, USDA, NRC, and DOE are taking in the regulatory evaluation of food irradiation.
3. Comments on the disinformation being utilized by the promoters of irradiation.
4. Specific comments on the text of H.R. 696.
5. Questions about food irradiation that CUFFs have not seen addressed.

Introduction

Thank you for the opportunity to comment on HR 696 and to raise questions about food irradiation. It appears that the FDA will be acting soon on the February 1984 proposed rule for the irradiation of fruits and vegetables, and the decision of this subcommittee will be crucial in the future of the governmental support for the commercialization of food irradiation. Please do not take your responsibility lightly. This is an extremely complex issue from a political, economic, scientific, and health perspective.

Consumers United for Food Safety is a Seattle, Washington based not-for-profit education and research organization working on issues such as food irradiation, direct farm marketing, organic farming, food coops, and pesticides. We have been especially concerned about the labeling issue with food irradiation, and are particularly disturbed about the changes inherent in HR 696 relating to labeling. The promotion of irradiation has also been wrought with misinformation and driven by political not scientific and safety concerns. This is extremely frustrating for consumers and scientists.

You may contact CUFFs at:

CUFFs
P.O. Box 22928
Seattle WA 98122

Linda Copper 322-6834
Don Norman 542-1275
Goldie Caughlin
(all 206) 322-1991

Organizational Support for Labeling and Further Research

CUFFs has presented 2 resolutions, one calling for labeling, and a second for further research to be performed prior to the acceptance of irradiated foods. Below is a partial list of organizations that have signed both resolutions. CUFFs has sent educational material to over 150 groups, but we are a small group, and have not had the time or resources to recontact them to find out if they have acted on the resolutions. We have generally found that most groups take a long time to act on them because the issue is complex, and they have little relation to their organization, and therefore get put to the backburner on board meeting agendas. Those groups we have contacted all support labeling; there have been some questions about the further research issue. Below are those that have signed both resolutions:

Group Health Cooperative Seattle, WA Both resolutions were passed at the annual meeting, and the labeling resolution was passed at the Governmental Affairs committee. GHC is an extremely large HMO in the state of Washington.

Puget Consumers Cooperative Seattle, WA. A 4 store, 35,000 member food coop.

Central Coop- Seattle, WA

The Food Co-op Portland, OR.

Puget Sound Cooperative Federation Seattle, WA

Northwest Nutritional Foods Association Seattle, WA

Greenpeace, Northwest Seattle, WA

Washington Public Interest Research Group Seattle,WA

Michigan Federation of Food Coops Ann Arbor, MI

Wheatsville Food Coop Austin, TX

People's Food Co-op Ann Arbor, MI

West Bank Coop Minneapolis, MN

Western Washington Toxics Coalition Seattle, WA

CUFFs has found that once groups understand what the issue is about, which generally takes quite some time read and digest, they support the labeling issue.

Comments on Procedures of Regulatory Agencies

CUFFs is completely baffled by the complexity and chaos in the regulatory procedures surrounding the irradiation issue. We would like to see some kind of interagency coordination of the issue, perhaps through the National Academy of Sciences, the Office of Technology Assessment, or under the National Environmental Polict Act. We have yet to find information from the Nuclear Regulatory Agency on the training and worker safety issues, plant construction impacts, transportation (or is that DOT or DOE jurisdiction?), and quality control of the doses the food will receive. The USDA has not responded, to our knowledge, to the pork ruling by release of inspection guidelines. This is of concern in light of the safety questions raised by the National Academy of Sciences report "Meat and Poultry Inspection", just published. We have been especially disappointed by the FDA. We have still not received any reply to our objections to the pork ruling (Docket #84F-0230 21 CFR Part 179). In our objections (FDA # HER-008) we noted that the ruling was released several days before the NEPA requirements would have necessitated an impact statement. You might note that it took the FDA 15 years to implement NEPA!

Comments on the disinformation in irradiation promotion

CUFFs is in the process of producing a pamplet entitled "10 Myths about Food Irradiation" to address the many misconceptions by the public about irradiation. The one that makes us most angry are the claims that "it's being done in 28 countries" (it changes each time). The best facts we can find (from pro-irradiation people) is that 10,000 tons of potatoes are being irradiated in Japan; that is less than 0.1% of the potatoes eaten (not produced) in the US. Claims that irradiation will cure hunger, provide an alternative to EDB, reduce pesticide use (as if we'll be irradiating the food while its growing), and how inexpensive it is continue to misinform consumers.

Within the FDA, there are also inconsistancies surrounding the risk assessment to risk management transition, as well as a lack of information surrounding the data used in risk characterization. In his statement before the House Subcommittee on Energy

Research and Production, Committee on Science and Technology on July 26, 1984, Sanford Miller said, "..with knowledge of the chemical changes occurring in irradiated foods, we can specify safe conditions of use by establishing the maximum doses of radiation permitted ...". This statement has already been hedged upon by the recent notice in the Federal Register (May 17,1985, Page 20624) that the FDA is allowing the increase of spice irradiation from 1 to 3 Megarads. The recent final rule on pork, with doses up to 100,000 Rads, will not get rid of all the bacteria, and it is obvious that it will be petitioned to be increased. The same testimony admits that should the percentage consumption of irradiated foods increase to be a significant portion of the diet, there would have to be a re-evaluation of potential effects. This assumes that there will be an average diet. More issues relating to the inconsistancies will be addressed as questions below.

Comments on HR 696

The basic intent of HR 696 is to alter the definition of irradiated foods, thus absolving the FDA from labeling requirements. Sid Morrison insists that the bill is "label neutral". CUFFs insists that there is no such thing as label neutral, and we demand that a clear label be devised for retail sales. This section should be inserted into the bill, with stipulations for packaged materials, fast food, restaurant menus, stickers for fresh fruits and vegetables, and other forms of retail sales. This does not have to be an offensive label, but a simple universal one. If irradiated food is so safe, let the marketplace be the judge. The potential backlash could be worse, causing extreme paranoia. Specific comments of the bill are as follows:

Section 2(a)5: irradiation is not just like microwaving etc.. Irradiation causes profound changes in the structures of the food. This is specifically why it is defined as an additive, though it is a process. While at the proposed doses, the effects of those changes may be difficult to detect, due to the low number of URPs produced, they are present in a proportional amount to the dose received. If you heat foods with room temperature air, they will not get hot. If the microwave isn't strong enough to rotate the bonds, the food will not get hot. Because irradiation is based upon rays of discrete energy, each single ray has the potential to create an URP.

Section 2(a)6: This section should be the responsibility of industry.

Section 2(a)8: It is not the government's role to promote acceptance, but to provide information and ensure safety.

Section 2(a)9: Some specific data should be presented to indicate if any US irradiation is ongoing, and the specific amounts of irradiation that are occurring in the "25" countries. This is misinformation.

Section 2(a)13: Some information on the costs of extracting the Cs^{137} from spent fuel rods and bombs needs to be presented to prove that the costs of "recycling" of nuclear waste is trully the cheapest and most efficient use of that material.

Section 2(a)14: The Department of Transportation needs to be included.

Section 2(a)15: The marketplace should do it.

Section #3 This has been discussed above. CUFFs has not had the time to examine Sections 201(s) and 409 of the Federal Food Drug and Cosmetic Act (21 USC 321(s) to supply the actual wording.

Section 6(b)1: The number should be increased to ten members, with three public members, one from each of the following areas: commercial food irradiation company employee, a food retailer/wholesaler with no irradiation ties, and a consumer advocate with no irradiation ties. Hopefully there will also be scientific advisors to this Commission.

This is probably the best idea of the bill, to serve as an informational and regulatory clearinghouse for information on irradiation and its uses.

Questions About Food Irradiation

Are accidents at food irradiation facilities to be covered by the Price Anderson Act? What are the regulatory actions, and chances for public input?

When proteins are irradiated, particularly small peptides, they form new compounds by crosslinking. What are the effects of this unuseable debris (URPs) in the body?

Do they cause allosteric competition during protein synthesis, thus altering the function of proteins formed? What about fats and carbohydrates?

Do they cause immune system responses? How does the body respond to foreign molecules (toxic or nontoxic) when there has been no previous exposure. What are the time and generational requirements to ensure safety?

Why are spices, which have the highest potential for producing toxic URPS, allowed to be irradiated? Is the justification solely based on consumption amounts?

Has research studied the types of surviving bacteria after irradiation, and looked into the production of toxins produced upon the death of the bacteria?

Is there one location, or bibliography that summarizes all this information? How can CUFFs obtain it?

Thank you for your attention to this issue.

Sincerely,

Donald Norman

Donald Norman, for CUFFs

WRITTEN TESTIMONY OF

BRIAN SPRINKEL*

BEFORE

THE HOUSE AGRICULTURE SUBCOMMITTEE
ON DEPARTMENT OPERATIONS, RESEARCH
AND FOREIGN AGRICULTURE

REGARDING

FOOD IRRADIATION AND WORLD HUNGER

NOVEMBER 19, 1985

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The idea that the domestic irradiation of food will alleviate world hunger is circulating in Congress. Washington State Representative, Sid Morrison, during a July 30, 1986 Congressional hearing on food irradiation stated that " [with food irradiation] we can take our current production of agricultural products and stretch it much further in reaching our helping hand around to other parts of the world." [1] California Representative, Leon E. Panetta writes in a letter to constituents, "Anti-hunger supporters believe that this [food irradiation] process will prevent food for overseas shipping to the hungry."

Humanitarian arguments like these calling for domestic food irradiation to study with recent mass media attention focused on Africa's present food shortage, but food irradiation as a technological hunger solution cannot be available only as long as we ignore political and economic realities of hunger. Africa's current drought has merely intensified the hunger, but poverty is the

root cause of famine. It is the chronically impoverished who die from drought, and Africa's impoverishment has been several hundred years in the making.

Balanced farming and herding systems that for centuries had adapted to changing environmental conditions gave way to European colonization. Fertile farm lands now grow sugar, cocoa, oil seeds, coffee, and cotton. These export crops have tied African Nations to the world food market. To feed their people these countries must compete with other nations.

Dependence on mineral and agricultural exports in return for food and manufactured goods is at the heart of Africa's hunger problem. Sudan, Ethiopia, Ghana, Gambia, Mozambique and 20 other African nations have a yearly food trade surplus.[2] This bitter irony is often created by large exports of one or two main food items. 70% of Ghana's total export income is generated from sales of cocoa. Gambia relies 90% of its export income from oil seeds and nuts. While world market prices for raw materials and agricultural products have stagnated or declined over time, prices of manufactured goods and processed foods have soared. By 1982 a full year's worth of African exports bought just 27 days worth of that continent's imports.[3]

This deterioration in Africa's terms of trade means that most African nations must fill the gap by borrowing. As these nations go deeper into debt, conventional [IMF] wisdom encourages boosting export crops to service the debt. As cash rolls in from sale of exports, much needed protein floods out to developed countries. After servicing their debt, developing countries have little resources left to buy food on the open market.

World food markets allocate food according to monetary wealth, not nutritional need. The six corporations that control 85% of world grain supplies are concerned with profit. While world grain reserves are at their highest level in history, Africans are starving in record numbers. [4]

Food distribution by monetary wealth is not the only stumbling block to feeding hungry people, food is also used as a political tool between nations. While Sub-Saharan populations go hungry, fully two thirds of of U.S. aid to Africa goes to just one country, Egypt. When in 1981 the government of Mozambique expelled several U.S. officials for spying, the Reagan Administration cut off all

Mozambique food aid while thousands in that country starved.

With these very real economic and political pressures in mind it is difficult to envision domestic food irradiation relieving hunger and suffering around the globe. Food irradiation is not an inexpensive treatment and will drive food prices up as much as 10¢ per pound depending on the food and dose rate.[5] This reality outlines the folly behind hopes that irradiated foods will find their way into poor countries. The foods now being irradiated in European countries are high priced, fancy foods like shrimp, frogs legs, papaya, fish, etc. If food irradiation will feed anyone it will be food buyers in developed countries with high per capita incomes.

Before we feed the world's hungry we must dispell the notion that people starve because they are geographically isolated. This idea is shattered with the realization that white South Africans enjoy one of the highest standards of living on the planet, yet they are geographically close to starving nations. South Africans eat well for the same reason that we do, they hold enough monetary power.

The idea that we need food irradiation as a high-tech treatment to save food that would otherwise spoil is a nonsense idea. Current food preservation techniques, like sun-drying fruits and vegetables, are proven, cheap, and licensed for use, what we need now is the humanitarian will to make real strides for food equity. Hunger in the developing countries is a serious problem worthy of this subcommittee's attention. Truely progressive ideas, if implemented can make great strides toward feeding hungry people, food irradiation is not one of them.

Footnotes

1. The Status of the Technical Infrastructure to Support Domestic Food Irradiation. Hearing before the House Science and Technology subcommittee on Energy Research and Production, July 26, 1984

2. FAO World Trade Yearbook, 1977

3. Africa's Debt Crisis , Interfaith Action For Economic Justice, July, 1984

4. Id.

5. Food Irradiation Update, Food Processing, June 1985, p.85

STATEMENT OF

Martin A. Welt, Ph.D.
Chairman, President and CEO
Radiation Technology, Inc.
Rockaway, New Jersey 07866

to the

Subcommittee on Department Operations, Research, and Foreign Agriculture

of the

COMMITTEE ON AGRICULTURE

U. S. HOUSE OF REPRESENTATIVES

November 18, 1985

Mr. Chairman, and members of the Subcommittee, we welcome this opportunity to provide testimony for inclusion in the record of hearing on the subject of food irradiation.

Radiation Technology, Inc., founded in 1968, has pioneered the commercialization of food irradiation in the United States. Without financial support or technical assistance from the government, we were solely responsible for obtaining the only FDA approvals for unrestricted food irradiation since 1964. Table I summarizes the extent of this accomplishment.

TABLE I

RECENT FDA APPROVALS FOR FOOD IRRADIATION

ITEM	DATE	REFERENCE
Spices, onion powder and garlic powder	7/5/83	48 FR 30613
Herbs, spice blends and vegetable seasonings	4/18/85	50 FR 15415
Dry or dehydrated enzyme preparations	6/10/85	50 FR 24190
Fresh pork and hog carcasses	7/22/85	50 FR 29658

Our company has known for some time that regulatory approval of the food irradiation process was only one step in the commercialization process. It is unfortunate that the benefits of this technology have been slowed, due in part to the inclusion of irradiated food within the food additive provisions of the Federal Food and Drug Act. We stongly urge passage of the proposed legislation introduced by Congressman Sid Morrison (HR696) in the House and by Senator Slade Gorton (S288) in the Senate, which would among other things classify food irradiation as a "process" similar to canning or freezing, which it is, rather than a food additive, which it simply is not.

On March 27, 1981, the FDA issued an Advanced Notice of Proposed Rulemaking for Food Irradiation (46 FR 18992). This proposal was based on a Bureau of Foods' Irradiated Food Committee Report which clearly concluded that <u>any</u> food could be irradiated to a dose of 100 krad (1.0 kGy) without any requirement for toxicological testing or any concern about the wholesomeness of the treated food. After 120 days of public comment, it took the FDA until February 14, 1984 to issue the Notice of Rulemaking on Irradiation in the Production, Processing and Handling of Food (49 FR 5714:5722). The delay of 21 months between these regulatory steps created a great deal of confusion within the food industry and gave time for the anti-food irradiation forces to mobilize their activities, which may be one of the reasons for the delay in issuance of the final regulation. It is fortunate that the Food and Drug Act specifies a fixed time frame for action on submitted food additive petitions otherwise no approvals would have been granted.

During the four years or so that we have patiently waited for the FDA regulation permitting the irradiation of fruit and vegetables for

insect disinfestation purposes or to delay maturation, Radiation Technology, Inc. designed, built and is operating commercial multipurpose computer controlled irradiation facilities capable of processing pallet loads of bulk food products at highly competitive prices. Our facilities have demonstrated the processing of Florida Indian River grapefruit at the rate of 1824 pounds per minute and fresh vacuum packed boneless pork loin at 2300 pounds per minute. We are working with pork producers who now realize the advantages they will have by not only offering a trichinae safe product but also one with a significant shelf-life extension under refrigeration. Some of the shelf life extension data is shown in a paper presented at the Annual Meeting of the National Seasoning Manufacturers Association in Chicago on October 23, 1985 which is included as Appendix A to our statement.

We presently operate commercial pallet irradiators at West Memphis, Arkansas and Haw River, North Carolina. Another facility is expected to go into operation at the Port of Salem. New Jersey early in 1986, and construction is now underway on a large food irradiation project at the Port of Elizabeth for the New York-New Jersey Port Authority. Based on actual operational experience we now know that insect disinfestation by irradiation can be accomplished for grapefruit, papaya or other agricultural products in an economical manner.

It is not necessary for the Department of Energy to go ahead with the construction of pilot irradiators planned for fruit and vegetable research in California or for pork irradiation in Iowa. Private industry has carried the ball so far, and in our view, it would be a violation of the Atomic Energy Act of 1954 for the DOE to compete with private industry. The facility planned for the Bay area of San Francisco, may be the only capital project ever built without first defining the research that will be performed. We were told that the facility would not compete with us, but we find that our customers are being solicited to see whether they will do their research at the DOE facility. Further, to say that we need these facilities for training is ludicrous. Where does the DOE think the personnel now operating the 40 or so commercial radiation processing facilities for medical product sterilization in the United States were trained?

This Committee may be interested to know that two of the petitions that we submitted to the FDA and which were approved, were paid for annonymously by major food companies. If we did not have that R & D income there might not have been any food irradiation approvals issued to date. Again without any government assistance, Radiation Technology, Inc. has submitted a petition to the FDA for the low dose irradiation of poultry to eliminate salmonella and to extend the refrigerated shelf-life. The final research in support of this petition was paid for by a large poultry industry association. Several other petition efforts are underway, on behalf of food company clients, ranging from fish and seafood to shelf stable meals of the type we now provide to the NASA space shuttle astronauts.

Mr. Chairman, it is vital that the United States embark on a crash program to provide cobalt-60 source material for the expanding radiation processing industry. Not to do so might place us at the mercy of a mon-

opolist, since the Canadian government produces about 90% of the world supply. We urge that the appropriation given the DOE for the above mentioned pilot/demonstration plants be rechanneled into source production activities and that those of us who have pioneered the commercialization of the technology be allowed to grow without government interference.

Mr. Chairman, during November 1984 I chaired a session on irradiated food safety at the Winter Meeting of the American Nuclear Society in Washington, D.C. At that meeting our panel of experts discussed the only articles found in the scientific literature which might imply an adverse food safety issue resulting from irradiation. Since no scientist with direct experience in the field of food irradiation agreed to serve on the panel and take a negative viewpoint, we invited several consumer activists, thinking that they would benefit from the open discussion, and modify their position. Unfortunately, our good intentions only resulted in their getting literature citations which they have used in their campaign against food irradiation. We expect that they will bombard this Committee with this information without providing the counterpart studies which in every instance have refuted the adverse citations. In a paper published by the Journal of Industrial Irradiation Technology, titled, "Barriers to Widespread Approval of Food Irradiation", 3:1, (1985), I discussed these issues in some detail and a further refutation is given in a paper by Dr. Ari Brynjolfsson, "Wholesomeness of Irradiated Foods: A Review", Department of Applied Biological Sciences, Massachusetts Institute of Technology, Cambridge, Massachusetts 02139.

The radiation preservation of food offers an unparalleled opportunity for the U.S. farmer to regain his competitive edge in world trade and to stop the decline of our agricultural exports. Time is running out for us in our race for market share as foreign nations adopt irradiation technology and discover that their fresh pork or papaya can reach the distant market that had been out of range.

This concludes my statement, Mr. Chairman. We would be pleased to provide additional information to you or your colleagues.

(Attachment follows:)

"SEASONED PORK---FOOD IRRADIATION PROGRESS IN 1985"

by

Martin A. Welt, Ph.D.

Radiation Technology, Inc.

Rockaway, N.J. 07866

presented at the

National Association of Seasoning Manufacturers Annual Meeting

Chicago, IL.

October 21, 1985

INTRODUCTION

As with most new technologies, food irradiation has had a long and frustrating period of gestation (1). Although more research has been conducted on this method of food preservation than any other, its commercialization has been slow in coming. Over the past 22 years, the FDA has approved only seven food irradiation petitions as required under the Federal Food, Drug, and Cosmetic Act (FFDCA), with three regulations being issued in 1985. The FFDCA considers any food intentionally exposed to ionizing radiation to be adulterated and subject to the food additive provisions of the Act. All recent approvals have significance for the pork and seasoning industry, and include: The sanitization of herbs, spice blends and vegetable seasonings; the sanitization of dry powdery enzymes; and the production of trichinae-safe fresh pork.

Another factor entered the food irradiation equation in 1985 for the first time and that involves the impact of the Federal Meat Inspection Act (FMIA) on the commercial introduction of the technology. With FDA approval of pork irradiation for trichinae control from a food safety point-of-view, the pork irradiation "process" now falls under the aegis of the USDA/FSIS with yet another set of rules and additional regulatory barriers to be overcome.

HERBS, SPICE BLENDS AND VEGETABLE SEASONINGS

On April 18, 1985, the FDA published in the Federal Register (50FR15415) an amendment to 21CFR179.22(b) approving the use of ionizing radiation to control insects and microorganisms in herbs, spices blends, and vegetable seasonings. The regulation set a maximum dosage not to exceed 10 kilogray (kGy) or 1 megarad (Mrad) and expanded the published list (49FR37851) of spices, onion powder and garlic powder to include the following:

Allspice; anise; basil; bay leaves; caraway seed; caraway, black (black cumin); cardamon; celery seed; chamomile; chervil; chives; cinnamon; cloves; coriander; cumin seed; dill seed; dill weed; fennel seed; fenugreek; garlic powder; ginger; grains of paradise (melaguta pepper); horseradish; mace; majoram; mustard seed; mustard flour; nutmeg; onion powder; orange petals; oregano; paprika; parsley; pepper, black; pepper, white; pepper, red; peppermint; poppy seed; rosemary; saffron; sage; savory; sesame seed; spearmint; star aniseed; tarragon; thyme; tumeric. Blends of the substances listed above may contain sodium chloride as a minor component.

The effectiveness of the irradiation process can be seen by noting the D-10 values for four typical herbs shown in Table 1. The D-10 value gives the dose in megarads (1 Mrad=10 kGy) necessary to reduce the stated microbial load by a factor of 10.

TABLE 1

D-10 VALUES FOR TYPICAL HERBS

Herb	Culture	D-10 Value (Mrads)
Licorice Root	SPC*	0.22
	G-**	0.19
Chamomile	SPC	0.26
	G-	0.24
Orange Petals	SPC	0.20
	G-	0.21
Peppermint	SPC	0.15
	G-	0.12

*standard plate count
**gram-negative bacteria

The D-10 values shown are typical for spices in general and predict typical count reductions of 3 to 4 logs for the existing maximum dose limitation of 1 Mrad. The FDA proposed (2) 30 kGy (3.0 Mrad) maximum dose for spices will render, in most cases, the treated product as "commercially sterile". In order to demonstrate the need for the radiation sanitization process for herbs, et al., Table 2 shows the microbial count data obtained for the products shown in Table 1. The data is based on an average of 10 replicates.

TABLE 2

AS RECEIVED BIOBURDENS FOR TYPICAL HERBS*

Herb	SPC	Coliforms	G-
Licorice Root	4,700,000	32,000	130,000
Chamomile	10,500,000	370,000	1,500,000
Peppermint	1,450,000	17,800	348,000
Orange Petals	9,460,000	1,120,000	2,210,000

*The average values of 10 replicates with a less than 10 count taken as 10 and greater than 37,000,000 taken as 37,000,000.

Other studies (3) were conducted on a herb tea constituent (Flores chamomillos) inorder to reduce microbial contamination. These flowers indicate the presence of thermophilic bacteria up to a level of 10,000 per gram. This material as well as many other herbs and spices often contain post harvest pesticide residues. The irradiation process was shown to be an effective alternative to chemical treatment for insect disinfestation. The chemical composition of the chamomile oil was monitored by spectroscopy, thin layer and gas chromatography. No harmful effect of the radiation treatment was found on any of the active components after sanitization.

Dry or Dehydrated Enzyme Preparations (including immobilized)

Enzymes comprise a minute fraction of the daily diet, even less than the small fraction comprised by spices. They act as a catalyzing agent when mixed with the target food product and are usually inactivated before consumption. As with spices, enzymes do not serve a nutritional purpose in the diet and hence any loss of enzymatic activity during the irradiation process is of little nutritional consequence so long as the catalyzing agent completed its task. The relatively low sensitivity of enzymes to radiation effects is of practical interest in foodstuffs because it is necessary to prevent enzymatic spoilage as well as microbial spoilage in preserving food. The inactivation of enzymes by moist heat usually coincides with the thermal destruction of vegetative forms of organisms. This is not the case with radiation preservation of foods. As a general rule, the complete inactivation of enzymes requires on the order of five times the dose required for the inactivation of the microorganism (4). On June 10, 1985 the FDA approved the use of Cobalt-60 or Cesium-137 for the sanitization and insect disinfestation of dry powdery or immobilized enzymes (50FR24190).

Dry powdery enzyme preparations, including protease, amylase, pectin depolymerase, and pectin methylesterase activities were irradiated with Cobalt-60 gamma rays. The results revealed a minor loss in enzymatic activity in the dose range below 10 kGy with microbial counts of less than 100 per gram (5). Experiments conducted by Radiation Technology, Inc. evaluated the irradiation sanitization of "typical" dried enzyme preparations. A liquid suspension of enzymes composed of lipase (major constituent) and protease (minor constituent) were spray dried on a combination of salt/starch and tricalcium phosphate substrates. The microbial assay of the dried enzymes are shown in Table 3.

TABLE 3

DRIED "TYPICAL" ENZYME BIOBURDEN

ITEM	COUNT PER GRAM
Total Bacteria	530,000
Total Enterics	< 10
Staphylococcus	< 10
Coliforms	< 10
Salmonella	Negative
E. coli	< 0.3
Fermentive	Negative

Triplicate samples were treated with varying doses from 0.0 to 40.0 kGy. As shown in Table 4, more than 99% of the detected microbial contamination was destroyed at a dose of 3.0 kGy. This large and significant reduction in microorganism count was accompanied by a 5% loss in enzymatic activity as shown in Table 5. As the dose is increased, the loss in activity increases as expected but at the 10.0 kGy maximum dose approved by the FDA (50FR24190), a high degree of sanitization can be expected with acceptable enzyme activity.

TABLE 4

DOSE TITRATION OF A "TYPICAL" DRY POWDERY ENZYME

DOSE (kGy)	TPC PER GRAM
0.0	515,000
0.5	345,000
1.0	91,500
3.0	1,100

Studies have been conducted using thin layer isoelectric focusing and gel filtration as a means of characterizing dry fungal pectinase before and after irradiation to a dose of 10.0 kGy (6). It was noted that charge and size properties were not changed to any significant extent. Similar results have been reported for Aspergillus oryzae and the bacterial protease Bacillus subtilis (7). Even at doses up to 200 kGy where losses in activity of up to 50% are found, there were no radiation induced changes in the charge and size properties. Because the physical and chemical properties of the "typical" enzyme preparations remain unchanged, it can be concluded that irradiation of this class of food additive is an efficacious method for the sanitization or sterilization of dry, powdery enzyme preparations.

TABLE 5

ENZYMATIC ACTIVITY AS A FUNCTION OF DOSE

DOSE (KGY)	PROTEASE ENZYMATIC ACTIVITY AS % OF INITIAL ACTIVITY	LIPASE ENZYMATIC ACTIVITY AS % OF INITIAL ACTIVITY
0.0	1.000	1.000
1.0	0.985	0.971
3.0	0.965	0.930
6.0	0.930	0.865
12.0	0.860	0.780
20.0	0.830	0.690
30.0	0.740	0.625
40.0	0.730	0.580

TRICHINAE CONTROL OF FRESH PORK AND HOG CARCASSES

On July 22, 1985 the FDA gave notice that the radiation preservation of food was here to stay by filing a notice in the Federal Register (50FR29658) which approved the irradiation of a major food item--fresh pork, at a dose not to exceed 1.0 kGy and no less than 0.3 kGy inorder to produce a trichinae-safe product. This approval was the fourth received by Radiation Technology, Inc. since the spice approval on July 5, 1983 and represents the only food irradiation approvals granted by the FDA since 1964 when approval was given for the irradiation of white potatoes to prevent sprouting and wheat and wheat flour for prevention of insect infestation.

Trichinosis is a serious infectious disease that has been known to man since antiquity. Although methods have been used to reduce the incidence of the disease by inspection of the meat, by freezing, curing or by recommended thorough cooking there still remains an inherent fear on the part of the consumer due to the small but finite number of cases of trichinosis reported each year. The Center for Disease Control still recognizes the disease as a serious public health hazard. This stigma regarding the consumption of pork has had an adverse impact on the economy of the pork industry. In fact, the National Pork Producers Council has passed a resolution, "to rid the pork industry of the trichinae organism."

It is well established that the larvae of the responsible organism, Trichinella spiralis, resident in the hog carcasses, are killed or made non-viable by a relatively low dose of gamma radiation (8). Investigators (9) have shown that a dose as low as 5 to 10 Gy (0.5-1.0 Krad) will substantially reduce the number of second generation larvae capable of encysting in the infected host after ingestion. If the dose is increased to 10-20 Krad, female larvae are sterilized and thus become incapable of producing second generation larvae and no encysted larvae have been found in infected hosts after consuming pork thus irradiated. At a dose of 30 Krads the encysted larvae in the pork (first generation) are killed upon ingestion. Recent studies (10) indicate a dose as low as 15 Krad prevents the emergence of first generation encysted larvae.

Because of the uncertainties associated with suppression of maturation of Trichinella larvae at the lower doses, it has been recommended that radiation as a public health measure be employed at levels that provide lethal doses (11). However, the higher doses needed to kill the larvae in the host are not necessary since no adult worms can survive in the enteric phase following irradiation.. The most recent studies have set the required dose between 20-30 Krads. Accordingly, the FDA regulation set a minimum dose of 30 Krads to provide for elimination of viable larvae in the ingested product.

There are no adverse effects of the irradiation treatment regarding the organoleptic acceptability of the product. Tests of flavor and odor of irradiated pork (even at much higher doses) have demonstrated no detectable changes (12). Moreover, the overall acceptability in the market place is enhanced by significant extension of shelf life, resulting from the concomitant irradiation induced reduction of spoilage bacteria. Esthetically, a benefit is derived also for those who may enjoy eating pork cooked to a lesser degree than now necessarily practiced to avoid the hazard of trichinosis.

Irradiation studies on exported product by Radiation Technology, Inc. have shown that at the volumetric average dose of 189 Krads delivered to 2300 pound pallet loads of fresh refrigerated boneless pork loin, vacuum packed, boxed and processed to a minimum dose of 150 Krads, the shelf life was found to be approximately 60 days. The unirradiated shelf life of the same product is "guaranteed" by the shipper to be 21 days (13). Table 6 summarizes the data for vacuum packed irradiated fresh pork. These date was taken by a customers laboratory in South Dakota after the samples were flown to Rockaway, N. J. for irradiation and returned while maintaining the refrigerated condition.

TABLE 6

SHELF LIFE PROJECTIONS

IRRADIATED FRESH VACUUM PACKED PORK LOIN

SAMPLE	PROJECTED SHELF LIFE (DAYS)* Surface	Whole Muscle
Control	27.4	27.4
0.075 Mrad	34.6	31.3
0.150 Mrad	48.0	39.2
0.300	Indefinite	Indefinite

* Samples tested for Standard Plate Count were considered at the end of the shelf life when the microbial counts reached 1,000,000.

Two of the 0.300 Mrad samples from Day 81 and Day 91 were cooked to 170 degrees F and tested for possible "off-condition" or rancidity due to their excellent color and no odor. The samples tasted like typical fresh pork and exhibited no off odors or flavors.

THE FEDERAL MEAT INSPECTION ACT

With FDA approval to irradiate pork for trichinae control, the commercial radiation preservation of meat came under the Federal Meat Inspection Act (FMIA), administered by the Food Safety Inspection Service (FSIS) of the USDA. Provisions for meat inspection by USDA were incorporated in the Departments appropriation approved March 4, 1907 (34 Stat. 1260, as amended). These provisions were completely revised by the Wholesale Meat Act, approved December 15 , 1967 (81 Stat. 584), which essentially designated the original provisions for meat inspection as the "Federal Meat Inspection Act" and as Title I of that Act, and added Titles II, III and IV to the Act. The Wholesale Meat Act consolidated into the FMIA the provisions relating to inspection of equine meat and food products thereof, and imports of meat and meat food products. Key portions of the FMIA relating to food irradiation are:

> Title I- Section 1(m)(7): The term "adulterated" shall apply to any carcass, part thereof, meat or meat food product if it has been intentionally subjected to radiation, unless the use of radiation was in conformity with a regulation or exemption in effect pursuant to section 409 of the Federal Food, Drug, and Cosmetic Act.
>
> Title I- Section 1(n)(1): The term "misbranded" shall apply to any carcass, part thereof, meat or meat food product if the labeling is false or misleading in any particular.

Rule 5a Sections Vlan. The term "Index" means a number of
articles, products, or products which can be combined
with excluding package content of the articles.

Rule 5a(1) Sec. The Secretary may by regulation prescribe
exemptions under which containers, parts of containers, and
such food products of parts, parts, or containers, and
other articles, capacity of one or fewer than, which do not
interfere with the functioning of the food, or which are
customary, or reasonably necessary for the packaging of the
food, shall not be considered to be misleading in violation
of this subsection. Such regulations shall be issued only
in accordance with the procedure prescribed in section 701(e)
of this Act.

Rule 5b(1)(A)(ii). Any determination made under section
403(h)(1)(A)(ii) of this Act shall be made on the basis of
all the information (including information submitted by the
petitioner) available to the Secretary as of the date the
determination is made.

Section 5b(1)(B)(ii)(I). Nothing in this subparagraph shall
be construed as requiring the Secretary to promulgate a
regulation establishing a reference amount customarily
consumed for any food or food category that is organized
primarily for sale or service at retail establishments.

Section 5b(1)(B)(iii). The Secretary shall establish
reference amounts customarily consumed for each eating
occasion identified by the Secretary pursuant to this
subparagraph. In establishing such amounts, the Secretary
shall consider the nutritional needs of individuals during
each such eating occasion, the role of food consumed at
each such eating occasion in the total diet of individuals,
and the amounts of food customarily consumed per eating
occasion by individuals.

Section 5b(1)(C)(i). The Secretary shall establish
procedures and guidelines for recognizing as the basis of a
nutrient content claim or a health claim a nutrient content
level specified by regulation adopted by the Codex
Alimentarius Commission. The Secretary may by regulation
permit the use of such claim in the labeling of food that
exceeds a nutrient content level established by such
regulation adopted by the Codex Alimentarius Commission if
the Secretary determines, based on the totality of the
publicly available scientific evidence, including evidence
from well-designed studies conducted in a manner which is
consistent with generally recognized scientific procedures
and principles, that there is significant scientific
agreement among experts qualified by scientific training and
experience to evaluate such claim, that such claim is
supported by such totality of publicly available scientific
evidence.

Section 5b(1)(C)(ii). Any regulation issued under this
subparagraph shall provide that a food may bear a nutrient
content claim or a health claim if a regulation has been
promulgated with respect to such claim and such food meets
the requirements of such regulation.

Section 5b(1)(C)(iii). Any regulation issued under this
subparagraph shall impose such conditions with respect to
the nutrient content of foods bearing such claims as may be
necessary to assure that consumers are informed about the
nutritional value of the food or the significance of the
nutrient in maintaining the overall nutritional quality of
the diet.

Section 5b(1)(C)(iv). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall meet the requirements
established by the Secretary for the nutrients of public
health significance in the food.

Section 5b(1)(C)(v). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not contain nutrients
in amounts which increase to persons in the general
population the risk of a disease or health-related condition
which is diet related for persons in the general population.

Section 5b(1)(C)(vi). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be deficient in
the nutrient which is the subject of the claim or in other
nutrients as the Secretary determines.

Section 5b(1)(C)(vii). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the level of any other nutrient in the food.

Section 5b(1)(C)(viii). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the presence in the food of an ingredient which may
increase the risk of a disease or health-related condition
which is diet related for persons in the general population.

Section 5b(1)(C)(ix). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the fact that the food is offered as a substitute
for a food for which such claim is commonly made.

Section 5b(1)(C)(x). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the fact that the food is intended to be consumed
in a quantity which would exceed the reference amount
customarily consumed per eating occasion.

Section 5b(1)(C)(xi). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the fact that the food is intended to be consumed
frequently.

Section 5b(1)(C)(xii). Any regulation issued under this
subparagraph shall require that a food bearing a nutrient
content claim or a health claim shall not be misleading in
light of the fact that the food is intended to be consumed
frequently.

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